

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al,
Plaintiffs,
v.
JOHNSON & JOHNSON, JANSSEN
PRODUCTS, L.P.
Defendants.

CIVIL ACTION NUMBER:
3:12-cv-07758-ZNQ-JBD
JURY TRIAL - VOLUME 21

Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608
June 11, 2024
Commencing at 9:00 a.m.

B E F O R E: THE HONORABLE ZAHID N. QURAISHI,
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

REESE MARKETOS
BY: PETE MARKETOS, ESQUIRE
JOSH RUSS, ESQUIRE
ANDREW WIRMANI, ESQUIRE
ADAM SANDERSON, ESQUIRE
WHITNEY WENDEL, ESQUIRE
750 N. Saint Paul Street, Suite 600
Dallas, Texas 75201
For the Relators

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
BY: ALLISON M. BROWN, ESQUIRE
GEOFFREY M. WYATT, ESQUIRE
BRADLEY A. KLEIN, ESQUIRE
One Rodney Square
920 King Street
Wilmington, Delaware
For the Defendants

Megan McKay-Soule, Official Court Reporter
Megan_McKay-Soule@njdcourts.gov
(690) 815-2319

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1 (PROCEEDINGS held in open court before The Honorable
2 ZAHID N. QURAIISHI, United States District Judge, on June 11,
3 2024, at 8:00 a.m.)

4 THE DEPUTY COURT CLERK: All rise.

5 THE COURT: Everybody have a seat. Good morning,
6 folks. Let's have appearances today, beginning with Relators.

7 MR. MARKETOS: Good morning. Your Honor,
8 Pete Marketos for the Relators.

9 MR. RUSS: Good morning. Josh Russ for Relators.

10 MR. WIRMANI: Good morning. Andrew Wirmani for
11 Relators.

12 THE COURT: Good morning, folks.

13 MS. BROWN: Good morning, Your Honor. Alli Brown for
14 Janssen.

15 MR. WYATT: Good morning, Your Honor. Geoff Wyatt
16 for Janssen.

17 MR. KLEIN: Good morning, Your Honor. Brad Klein for
18 Janssen.

19 THE COURT: All right. Good morning, folks.

20 I just have to get my jury instructions, which are on
21 my desk. So let me get those, but I think for this morning
22 all I want to address are the jury instructions. We can deal
23 with the verdict sheet and other things during lunch break
24 because I don't need to have those finalized and we don't need
25 to have that discussion before I give the final instructions,

1 so why don't we just start off where we left off yesterday.

2 Mr. Russ, are you addressing the Relators' concerns
3 with the jury instructions or the --

4 MR. RUSS: Yes, Your Honor.

5 THE COURT: -- proposed revisions? All right.

6 Why don't we -- what I'd like to do is I just want to
7 hear from Relators first, go through those. I'll hear
8 Janssen's responses to those, and then I'll give Janssen an
9 opportunity to talk about some instructions that they want to
10 talk about, and then hopefully within this hour we can
11 finalize those, if that works for everybody.

12 And then what I think we're going to do is I'll give
13 the final instructions, then we'll take a ten-minute break,
14 because I think that's going to take some time. That also
15 gives Relators a chance to reboot. And then we'll take a
16 break probably for lunch for splitting the closings. And
17 after Janssen, I'm going to give a ten-minute break before
18 rebuttal, just so there's a little bit of a break between
19 each. That way, if the jurors need a break or counsel needs a
20 break, we have those.

21 But other than those -- Mr. Marketos, do you have
22 something to say on that?

23 MR. MARKETOS: Only this, Your Honor. The -- we'll
24 need time to get the special verdict form into our
25 presentation. Right? We need to make sure that we have the

1 opportunity to address how it's filled out, and so we are
2 going to be scrambling to do that. Could we --

3 THE COURT: You want to talk about the verdict sheet
4 this morning, then?

5 MR. MARKETOS: If that's okay, because we obviously
6 need to walk through it, you know, and --

7 THE COURT: All right. Well, hopefully you guys
8 won't take up an hour on the jury instructions, and then we
9 can talk about verdict sheets. So hold on one second.

10 Can you get me my verdict sheet. All right. Let me
11 get my -- what I propose is going to be the verdict sheet so
12 that we have a better sense of it, and then we can talk about
13 it.

14 But all right. Let's go through the jury instructions.
15 And then I appreciate that comment about -- it might be nice
16 for you all to know what the verdict sheet is going to look
17 like for purposes of closing, so let's see if we can address
18 that.

19 So Mr. Russ, where did we leave off? Let's just go to
20 the beginning since yesterday the first instruction you guys
21 talked about, I didn't have a sense of, you know -- what I'd
22 like to know is, if you guys have a proposed revision
23 somewhere, is there legal support for your proposed revision;
24 if so, what is it. If not, if it's stylistic, that's fine,
25 but let me know where you're coming from so I'm not pulling up

1 regulations or statutes to figure out if I missed a word or
2 where you're coming from.

3 And also, do you guys want to approach? Because I can
4 at least -- Kim, do you mind?

5 THE DEPUTY COURT CLERK: Sure.

6 THE COURT: Give these guys -- I at least want to
7 give you a version of the verdict form that I put together
8 with my folks, and then we can talk about it.

9 All right. But let's talk about the instructions.

10 So, Mr. Russ, where do you want to begin?

11 MR. RUSS: So, Your Honor, we have conferred, and all
12 of the items that I want to discuss today, which I think will
13 take less than five minutes, hopefully, are either stylistic
14 or are agreed with Janssen's counsel.

15 THE COURT: All right. So that may be quicker, but
16 let me hear from you and then --

17 MR. RUSS: Sure.

18 THE COURT: -- we'll go from there.

19 Which number am I going to?

20 MR. RUSS: I'm looking at -- I think it's the --
21 hopefully the red line is the right number. It's number 22 on
22 page 27 of my copy.

23 THE COURT: Yep. So let me go to the red line and
24 then -- sure. Yep.

25 MR. RUSS: Where it says, "Coverage for drugs may,"

1 I've talked to Mr. Wyatt, and I think it's agreed that we
2 would add the word "also" after "may."

3 THE COURT: Right. No objection, Mr. Wyatt, if I'm
4 going to give that instruction?

5 MR. WYATT: Right. Subject to our objection to the
6 language overall, no problem with "also."

7 THE COURT: All right. So for now until I hear from
8 Mr. Wyatt as to whether something's going to be stricken
9 completely out of here, I'll add "also" after "may," if that's
10 how it remains.

11 What else, Mr. Russ?

12 MR. RUSS: Thank you, Your Honor.

13 On page 28 -- this is Instruction Number 23 --

14 THE COURT: Right.

15 MR. RUSS: -- there is a reference to "record
16 evidence." I've talked to Mr. Wyatt. I believe that language
17 comes from *Greenfield*, but it's only in one instance in
18 *Greenfield*, and most of the instances it does not have the
19 word "record." I think it's because it's a summary judgment
20 case.

21 THE COURT: It reads, "was" -- "There was some
22 evidence of a link." Is that what you're looking for, is to
23 strike the word "record"?

24 MR. RUSS: So to strike the word "record" and then
25 add "some evidence in this case of a link."

1 MR. WYATT: No objection.

2 THE COURT: All right. So it will read, "Some
3 evidence in this case of a link." I don't have any issue with
4 that change as well.

5 What else, Mr. Russ?

6 MR. RUSS: And, Your Honor, just to reflect the same
7 change, I believe the same language appears in Number 23.3 on
8 page 32.

9 THE COURT: Bear with me.

10 (Brief pause.)

11 THE COURT: Right. So you would have that read the
12 same way, right? "There was some evidence in this case."

13 MR. RUSS: Correct, Your Honor.

14 THE COURT: All right. I made that.

15 Keep going.

16 MR. RUSS: Okay. Your Honor, Number 24.3 on page 41,
17 the second line says, "submitted to the federal government."
18 We have conferred with -- I have conferred with Mr. Wyatt
19 about the removal of the word "federal" in that instance
20 because some of these claims can be submitted to Medicaid,
21 which would be a state government, and I believe that's
22 agreed.

23 THE COURT: Mr. Wyatt?

24 MR. WYATT: Just one minute, Your Honor.

25 (Brief pause.)

1 MR. WYATT: Yeah, no objection.

2 THE COURT: All right. I'll strike the word
3 "federal" before "government."

4 MR. RUSS: Your Honor, the next one is an unnumbered
5 instruction on page 48 regarding the corporate integrity
6 agreement.

7 THE COURT: All right. So we need to add a number in
8 there, but I guess we'll do that on our end.

9 MR. RUSS: Since the time this was read during the
10 case, Your Honor, there was also discussion about a 2010
11 settlement. And so the proposal would be, on the second line,
12 "as well as settlement agreements in 2010 and 2013." And I
13 believe that's also not opposed.

14 MR. WYATT: No objection.

15 THE COURT: All right. So I will make that change.
16 So "as well as settlement agreements," plural, and then add
17 2010 in there, not just the 2013 one that I initially inserted
18 back in the day.

19 MR. MARKETOS: Correct, Your Honor.

20 THE COURT: All right. I'll make that change. Is
21 that the only spot where that comes up, Mr. Russ, from your
22 review? I think so. I don't think I have another instruction
23 regarding these CIAs or the settlement agreements, but I just
24 wanted to make sure.

25 MR. MARKETOS: I think you're right, Your Honor. On

1 the next sentence it says, "The corporate integrity
2 agreements" and then "settlement agreement," I guess --

3 THE COURT: Let's -- I'll make that plural. And then
4 it comes up later as well.

5 MR. RUSS: It comes up later --

6 THE COURT: All right. I'll make the universal
7 change that after we reference 2010 and 2013 where it
8 references "settlement agreement" throughout that instruction,
9 I will make it plural.

10 MR. RUSS: Thank you, Your Honor.

11 THE COURT: All right.

12 MR. RUSS: One last one that I have, Your Honor, and
13 this one is opposed. It's on Instruction Number 28.

14 THE COURT: Sorry. What page are we on?

15 MR. RUSS: Instruction 28 on page 56.

16 THE COURT: Okay, 56.

17 MR. RUSS: This was an error, I believe, in Relators'
18 original proposal. If you look at the top sentence,
19 Your Honor, it says, "the amount of money that the government
20 paid out by reason of the false claims." That's the normal
21 test for a False Claims Act case. But if you go to the second
22 paragraph, it then says, then, "the full amount paid to
23 Janssen." And that should --

24 THE COURT: Paid to the government?

25 MR. RUSS: It should be "the full amount paid by the

1 government."

2 THE COURT: Got it.

3 MR. RUSS: But I believe that Mr. Wyatt opposes that
4 change.

5 THE COURT: All right. Hold on one second. Let me
6 read it, then, if there's going to be an objection.

7 (Brief pause.)

8 THE COURT: Mr. Wyatt, let me hear from you on that
9 one, then.

10 MR. WYATT: Yeah, Your Honor. This is one that is
11 proposed by the Relators, and the issue is that there may be a
12 difference between the amount the government paid in the first
13 instance and the net out of pocket to the government because
14 there were rebates. And so our argument under the case law --
15 and this was addressed in the trial briefing -- is that the
16 proper measure is the amount that was paid back to Janssen,
17 because that is -- or the amount ultimately received by
18 Janssen, because that reflects the rebates that would have
19 been paid to the government. And so that's the proper measure
20 here.

21 THE COURT: I mean, I remember this rebate issue.
22 What evidence was there in the case about rebates?

23 MR. WYATT: I believe this came up in the examination
24 of Professor Shaked about his numbers and whether they
25 reflected the rebates that were paid to the government by

1 Janssen.

2 THE COURT: Mr. Russ?

3 MR. RUSS: Your Honor, I believe they lost that
4 argument during a sidebar. But the full amount paid to
5 Janssen wouldn't even reflect the rebate. I'm not sure how
6 that makes sense, the rebates would be paid back to the
7 government.

8 I am not aware of any case that measures the False
9 Claims Act damages by the amount that is received. It's the
10 amount paid. And that's why the first sentence is correct but
11 the second sentence was inadvertently changed, and it's not
12 the right measure.

13 THE COURT: All right. I appreciate your arguments.
14 I'm going to revise the language to read, then, "the full
15 amount paid by the government," which the Relators are
16 suggesting. I think that's consistent with my prior ruling
17 during the trial and also consistent with the rest of the
18 instructions. So that's how I'm going to leave that. But
19 Janssen's objection is noted.

20 Where else are we going next after that, Mr. Russ?

21 MR. RUSS: Your Honor, I believe that's all we have
22 on the jury instructions.

23 THE COURT: All right.

24 Mr. Wyatt, where do you want to begin? Do we have a
25 lot here or --

1 MR. WYATT: It shouldn't take that long. I have a
2 little bit more, Your Honor, but I don't think it will take
3 very long.

4 THE COURT: Where do you want to take me?

5 MR. WYATT: I just want to start just procedurally,
6 you know. Under Rule 51(c) we have to -- "A party who objects
7 to an instruction or the failure to give an instruction must
8 do so on the record, stating distinctly the matter objected to
9 and the grounds for the objection."

10 I understand the Court doesn't want us to go
11 instruction by instruction, and I don't either, so we -- I
12 believe this obligation will be satisfied to the extent I
13 don't address anything specifically here by referring back
14 to --

15 THE COURT: Yeah. I mean, Mr. Wyatt, I don't want to
16 cut you off from a record of objecting to an instruction just
17 because I've included it.

18 So if you think it's sufficient -- I think it's
19 sufficient to say, look, we're referring to all of our
20 objections in the past, even if Your Honor has ruled against
21 that as an included instruction or a rejected instruction that
22 we proposed.

23 But if you think you need more -- to do more than that,
24 then I'm going to give you the opportunity to do it this
25 morning. I just think that's sufficient for the record. I'm

1 not contesting or in any way stating on the record that you've
2 waived your prior objections by only focusing on what I
3 provided you in the final instructions. And I'll make it very
4 clear you have not waived those objections. Those objections
5 are noted. They still exist in the case. If you think that's
6 sufficient, then it can save us some time.

7 MR. WYATT: It will save us a lot of time. I'm only
8 going to focus on a few things, some which I think are
9 contested. The other thing I just want to mention is those
10 submissions, the joint submissions the Court considered here,
11 they are not actually on the record. They were sent by email.
12 So what I would proposed to do with that and a couple of other
13 email correspondences with the Court over the course of the
14 trial is for us to submit a proffer on the docket that
15 attaches those things, that they're there. That will sort of
16 be the backdrop for what --

17 THE COURT: Yes, so at least you have them on the
18 record.

19 MR. WYATT: Yes.

20 THE COURT: At least in the public docket for any
21 issue on appeal. That's fine.

22 MR. WYATT: Right. Right. Okay. So starting out
23 with agreed Instruction Number 14 regarding the use of
24 depositions --

25 THE COURT: What page? I'm still on the red line.

1 What page is that?

2 MR. WYATT: Page 18.

3 THE COURT: All right.

4 MR. WYATT: So this -- I don't know if this is
5 opposed or not. Relators said they were considering this last
6 night.

7 Do you guys have a position?

8 I think it should be taken out because it's really
9 about the affirmative use of depositions for substantive
10 evidence. The commentary to the model says the instruction is
11 not appropriate if answers -- meaning answers in the
12 deposition -- are --

13 THE COURT: I see. So, Mr. Wyatt, your take -- you
14 don't have to read it. Your take is that, you know, say a
15 witness was unavailable and we played that witness's
16 deposition for purposes of trial, you think this instruction
17 is more tailored to that scenario, not the one in which both
18 of you are going, for purposes of impeachment or otherwise,
19 playing deposition transcripts.

20 MR. WYATT: Correct.

21 THE COURT: Mr. Marketos -- I'm sorry. Mr. Russ.
22 One of you.

23 MR. MARKETOS: Your Honor, I think it needs to stay
24 in. In particular, in this case, depositions aren't just
25 played for impeachment. They're party opponents, so they're

1 admissions, and so they need to understand that, when it's
2 being played, it's just as if the testimony is being offered.

3 THE COURT: Have you guys worked out which
4 depositions or which deposition portions are admitted for
5 purposes of going back as evidence for the jury and which
6 haven't?

7 MR. MARKETOS: I don't think that -- I don't think
8 that -- well, I think we'll usually -- that's a good question,
9 Your Honor. We don't usually do that. I think the jurors
10 just accept what they hear. It doesn't get recorded on the
11 court's transcript, so it's just based on upon what the --

12 THE COURT: No. I guess what I'm trying to say is if
13 you're telling me that there are some deposition transcripts
14 that have been admitted into evidence, right, they weren't
15 just used for purposes of impeachment, but you've somehow
16 admitted them -- I mean, every week, you guys are going
17 through which evidence goes back with the jury for
18 deliberations. If a piece of evidence is admitted, whether
19 it's video, audio, or documentary, that should go to the jury.

20 MR. MARKETOS: Yes.

21 THE COURT: I'm not clear on which depositions have
22 you all agreed on had been admitted into evidence, which then
23 mean the jury should have that in deliberations. It shouldn't
24 be something that -- well, they heard it at trial. That would
25 mean, like, you showed a document during trial and even though

1 it's been admitted, it doesn't go back to the jury to review.
2 That doesn't make any sense to me.

3 MR. MARKETOS: No, Your Honor. It's just like
4 testimony. So we're not sending the trial transcript back
5 with them. So when you play a deposition into transcript,
6 they hear it just like they hear testimony from the witness
7 stand. It's not a separate exhibit. So the only point that I
8 was making there is, yes, there are instances where you would
9 play an exhibit -- excuse me -- play a deposition and that
10 would be evidence for the members of the jury just like the
11 witness was in the courtroom. And we have instances of
12 deposition clips being played and used on the ELMO. So they
13 do need to understand that that's sworn testimony. I think
14 the instruction is appropriate. But it doesn't go back to the
15 members of the jury. It's just they received the testimony
16 just like they did somebody testifying from the box.

17 THE COURT: All right. Mr. Wyatt.

18 MR. WYATT: I mean, this is the first I'm hearing of
19 this position. We haven't talked about whether there's any
20 deposition played here that's being proffered for the truth of
21 the matter asserted. I don't think that's the way it came in,
22 and certainly no one has designated it as an exhibit, as
23 Your Honor indicated, but ultimately, I'm just trying to
24 streamline the instructions. I think this instruction is
25 potentially confusing because I believe most of the deposition

1 testimony, if not all of it, at trial was used for impeachment
2 purposes. But I'm not going to die on this hill if it makes
3 sense to give the instruction for --

4 THE COURT: Let me take a look at it, if you folks
5 will give me a moment. I just want to reread the use of
6 deposition instruction.

7 (Brief pause.)

8 THE COURT: Let me ask you this, Mr. Marketos.

9 MR. MARKETOS: Yes, Your Honor.

10 THE COURT: What if I instructed on the first
11 paragraph and not the second, which just educates the jury to
12 what a deposition is?

13 MR. MARKETOS: Fine, Your Honor.

14 THE COURT: Because I kind of -- I understand
15 Mr. Wyatt's argument. I don't want to confuse the jurors, but
16 at the same time, I do think it is not inappropriate to remind
17 them in an instruction kind of what a deposition is and it's
18 sworn testimony and that.

19 And so, Mr. Wyatt, my inclination -- and there seems to
20 be no objection from Relators -- is to just remove that second
21 paragraph but just instruct them briefly on the first
22 paragraph.

23 MR. WYATT: No objection.

24 THE COURT: All right. So that's -- there you go.
25 What's the next one?

1 MR. WYATT: 2.6 is not in the instructions. So 2.6
2 is the use of interrogatories. Among the exhibits we plan to
3 move in -- and that's a separate issue that we may need to
4 address before the jury gets in here because they are opposing
5 all of our exhibits as untimely --

6 THE COURT: Why didn't you move -- I'm sorry. Why
7 are you moving -- the only exhibit that I'm aware of that is
8 pending is the FDA regulation that you guys all wrote about
9 that I asked for Relators to respond to, and I just read it
10 this morning. What are these additional exhibits that you
11 guys are trying to move in after you've already rested?

12 MR. WYATT: This came up two days ago. Yesterday
13 sent them a list of the exhibits that we wanted to move in.
14 We rested subject to resolving that list of exhibits. We
15 didn't get a response from them last night as to whether they
16 were going to oppose --

17 THE COURT: I mean, I haven't been made aware of it,
18 though. It's not like you advised the Court that -- when you
19 said you rested subject to the admissibility of evidence, the
20 only one I was aware of is the FDA regulation.

21 MS. BROWN: Your Honor, I do believe I raised it as
22 at sidebar yesterday when the Court inquired if we had rested,
23 and I said, yes, subject to exhibits. I referenced at sidebar
24 that we had emailed them a list yesterday morning. And
25 Mr. Russ asked, you know -- understandably, they were busy

1 during the day. Could they have the night to look at them.
2 Most of them I'm surprised to hear there's an objection --

3 THE COURT: Why didn't you move to admit them in your
4 case, though? Why did you wait and rest reserving this? Why,
5 while you guys had the case, did you not attempt to move in
6 these additional pieces of evidence?

7 MS. BROWN: What they really are, Your Honor, is --
8 for example, we moved in five of the six guidelines, and as we
9 were putting together the closing, we realized Alli forgot to
10 move in 2008. So there's a stray list of items that to be --
11 were discussed, were talked about, are noncontroversial, but
12 I'm surprised to hear there's an objection.

13 THE COURT: So we -- sorry. Take me back to where we
14 are, then, Mr. Wyatt. What instruction is this?

15 MR. WYATT: It's 2.6, which is about the use of
16 interrogatories, because one of the exhibits or maybe two of
17 the exhibits we're seeking to move in are interrogatory
18 responses.

19 THE COURT: Mr. Marketos, first of all, is there an
20 objection?

21 MR. MARKETOS: Yes, Your Honor. It looks like it's a
22 list of about 30 documents, including --

23 THE COURT: I'm talking about the interrogatories.
24 Isn't that what we're talking about first? I'm not talking
25 about the laundry list of documents they're looking to move to

1 admit that they might have reached out to you to confer on.
2 What about this instruction specifically?

3 MR. MARKETOS: The instruction. I'm sorry.

4 THE COURT: What's the instruction, Mr. Wyatt? I
5 don't have it before me because it looks like one I wasn't
6 provided or I didn't give you all in the final instructions.

7 MR. MARKETOS: There are no interrogatories in
8 evidence.

9 MR. WYATT: May I approach?

10 THE COURT: You may.

11 Mr. Marketos, I get it that there's no interrogatories
12 in evidence. It sounds like they're moving to admit
13 interrogatories in evidence. It sounds like they are moving
14 to admit interrogatories in evidence and that's why they're
15 asking to include the instructions.

16 Mr. Wyatt, is that accurate?

17 MR. WYATT: Correct.

18 THE COURT: Well, I think -- I have two things to say
19 about it. If I was going to give this instruction, I think I
20 would do exactly what I did with use of deposition. I would
21 give the first paragraph and strike the rest of it because I
22 think that's consistent with what we all agreed to do with use
23 of deposition. But the threshold issue is I'm not giving this
24 instruction if there are no interrogatories in evidence. So
25 where are we on that issue?

1 MR. MARKETOS: There are no interrogatories in
2 evidence. It looks like they are trying to make up the rest
3 of their case with late-submitted documents, and there are
4 about 30 of them. Are we going to submit the amended
5 responses? There are CFRs on this list; there are
6 interrogatories on this list. It looks like basically they're
7 trying to fill gaps in their evidence by offering a bunch of
8 documents.

9 THE COURT: I have concerns about this, too. I still
10 don't understand. What is this that you guys are now trying
11 to move into evidence? Again, my understanding was that the
12 FDA regulation was the only evidence that we would need to
13 address. That's the only evidence pending before the Court
14 that's in dispute.

15 Why didn't you submit these pieces of evidence? It's
16 not like you just learned about the interrogatories now.

17 MR. WYATT: We were trying to allow time for the
18 Relators to evaluate and decide whether they had any
19 substantive objections to the exhibits. We believe that we
20 raised this at sidebar yesterday and said we are resting
21 pending moving additional exhibits into evidence. Most of
22 these things are policy documents by the company which have
23 been used at trial with various numbers of witnesses. And the
24 guidelines. There are a few other documents.

25 THE COURT: Outside of the interrogatories, what are

1 the other documents?

2 MR. WYATT: The other documents are --

3 MR. RUSS: Your Honor, you want me to send the email
4 to Ms. Stillman and copy Mr. Wyatt so you can see the list?

5 THE COURT: Yeah. Actually, put it to all my folks,
6 my law clerks, too.

7 MR. WYATT: So there's six additions of the
8 guidelines. There are several policy documents from Janssen
9 of the sort that we've seen at trial regarding, for example,
10 speaker bureau policy, promotion policy, et cetera.

11 THE COURT: Yeah, but here's what I don't understand.
12 Right? If you had moved to admit these documents and the
13 Relators had an opportunity to respond, you're trying to move
14 in a myriad of documents at the closing of the case. I mean,
15 I think this is unfair to the Relators. I mean, to me this
16 doesn't make any sense. I still don't understand what
17 documents are you moving to admit now that for some reason,
18 during your case in chief -- or I'm sorry -- your defense case
19 you couldn't move to admit?

20 MR. WYATT: We're just doing the same things the
21 Relators did, Your Honor, they moved in batches of documents
22 without any witness as well. I mean, this is just cleanup
23 that happens routinely in the cases that I've been in where at
24 the close of the case, there are a couple of exhibits that are
25 self-admitting, they're self-authenticating, or they are

1 exceptions to the business record hearsay rule and you just
2 move in. There's no --

3 THE COURT: The interrogatories is not my concern.
4 What are the additional documents other than the
5 interrogatories?

6 MR. WYATT: They are largely what I've described. So
7 number 1, various additions of the DHHS guidelines, which are
8 government policy documents; and business documents like the
9 sort that we've seen at trial; you know, how to do a speakers'
10 bureau; how to establish fair market value; et cetera.
11 They're clearly business records of the company.

12 THE COURT: What documents are in dispute,
13 Mr. Marketos?

14 MR. MARKETOS: Well, we really need to go through
15 them, Your Honor. They sent them to us during trial
16 yesterday, and we've got about -- it really is like a bit of
17 an ambush.

18 THE COURT: I mean, the interrogatories aren't. I
19 mean, those are the statements from the Relators?

20 MR. WYATT: Yes, Your Honor.

21 THE COURT: I mean, that one is not a concern for me,
22 to be candid with you. And, look, Mr. Wyatt makes some point
23 that you all were able to move in some documents, too, but my
24 point is, what are the other documents?

25 And I'm still a little bit confused as to why this is

1 being done now on the eve of me giving these final
2 instructions. I just don't understand it, and I don't
3 understand why the Court wasn't made aware of these documents,
4 other than the FDA regulation, which I intend to address this
5 morning.

6 MR. MARKETOS: I don't understand it either, and are
7 we going through now -- the only reason we admitted any
8 documents was because Your Honor ordered them to be entered.
9 That was the documents relating to --

10 THE COURT: HCC compliance investigation docs.

11 MR. MARKETOS: Yeah, exactly. We didn't come in with
12 a whole set of documents that we wanted to introduce that, you
13 know, hadn't come in during our case in chief. They've had
14 all case to present this evidence, and now we're going to go
15 line by line and counter with our own exhibits that they're
16 trying to offer?

17 THE COURT: Ms. Brown?

18 MS. BROWN: Yeah, perhaps I can offer a little
19 explanation because it's really my practice.

20 So when I put together a closing, Your Honor -- and I
21 have a slide that talks about the guidelines -- my folks cite
22 the stuff on the bottom, and then they say, Alli, you only
23 moved in these years; make sure to get this in.

24 And so as the closing gets put together, Your Honor,
25 where I am closing on evidence and documents and testimony

1 that comes into the case, but I want to properly represent on
2 the slide that I moved in every single year. We have a
3 running list.

4 THE COURT: Yeah, but that -- I appreciate that
5 practice, but I don't think it's a good one. I mean, the
6 practice should be, these are the documents we need to get in
7 evidence in order to close on these issues. And that should
8 be done while the case is going on, not, the case is closed;
9 we're about to instruct the jury, and now we're thinking, We
10 forgot to admit certain pieces of evidence, and I need these
11 pieces of evidence in. I mean, I don't find that to be a best
12 practice at all, whether it's the practice you guys do or not.

13 What you're telling me is, We forgot to admit evidence
14 during the trial. And so now we want to move this evidence in
15 because when we were formulating our closing argument, we
16 realized that there are pieces of evidence we have not
17 actually admitted or moved to admit before the Court. And
18 that's troubling.

19 MS. BROWN: I guess not quite, Your Honor. I mean, I
20 would say some of these exchanged as early as in opening, and
21 counsel said no objection, and just over the course of the
22 trial, they never formally got moved in.

23 I never would have rested the case, Your Honor, and
24 that's why I rested only subject to this. Many of them have
25 been discussed. They've been discussed with witnesses.

1 They've been discussed with counsel. They are now on a final
2 list. They are independently admissible, and we seek to admit
3 them for use in closing.

4 THE COURT: All right. Well, now we have to go
5 through these because there are objections to all of these
6 documents, correct?

7 MS. BROWN: I don't know, Your Honor. We sent --

8 THE COURT: Mr. Marketos, are there objections to
9 these documents?

10 MR. MARKETOS: There are going to be, Your Honor.

11 THE COURT: Right. So then here we are. We're going
12 to deal with it this morning. And now the jury is going to be
13 delayed and all because this is the practice that you guys are
14 telling me somehow that should guide me.

15 That's not a good practice. Because now we are dealing
16 with these objections this morning. It was not on the agenda.
17 Nobody advised the Court about any of the particularities of
18 these documents or that there were going to be any disputes
19 other than the FDA regulations.

20 So let's go, one by one.

21 And Mr. Wyatt, this cuts into your time because I
22 thought we were going to talk about jury instructions. But
23 now we're going to be talking about 30 documents that you guys
24 are moving to admit at the end of the case, and now we have to
25 address them one by one. Right? That's what we're going to

1 do.

2 MR. WYATT: Yes, Your Honor.

3 THE COURT: All right. Let's do it.

4 So what's the first one, interrogatories?

5 Mr. Marketos, do you have something you want to say?

6 MR. MARKETOS: Yes, Your Honor. Just to be clear, I
7 don't believe that they preserved the right to enter documents
8 after they closed.

9 THE COURT: Well, I do remember -- and I will be
10 clear. Ms. Brown did make that indication to the Court. I
11 think, if anything, it was misleading to me because I was not
12 aware that there were 30 other documents that you were all
13 disputing that now we're going to address this morning.

14 But there is a record of Janssen's stating that they
15 rest with that one caveat, of moving in certain exhibits.

16 Now, if I knew that this is what you meant by it, I
17 would have scrutinized this issue when it was said to me on
18 the record. But there is a record made of it, and now I have
19 to address it.

20 I'm not happy about it. I think I made that clear.
21 But I'll with deal with it.

22 MR. MARKETOS: I thought they were referring to the
23 filing because they apparently sent us an email during trial
24 with a list of exhibits.

25 THE COURT: Yeah, so did I. But the point is, there

1 is a record made and I'm not going to -- I don't think it was
2 clear, but I'm going to review this issue, I guess, in a light
3 most favorable to Janssen since they're the one who placed on
4 the record that they were closing pending the admissibility or
5 moving in some documents into evidence. So let's go through
6 these one by one.

7 Your objection is noted from the Relators, but let's go
8 through it.

9 So what's the first document?

10 MR. WYATT: The first document is 1058, and 1058,
11 1059, 1063, 1064, 1066, and 1067 are all editions of the DHHS
12 guidelines.

13 THE COURT: No, I thought we were on interrogatories.

14 MR. WYATT: I'm happy to start there, Your Honor.

15 THE COURT: Well, let's start there since I'm still
16 looking at the instruction.

17 MR. WYATT: They are D-2370 and D-2371.

18 THE COURT: And those are the responses from the
19 Relators?

20 MR. WYATT: Ms. Brancaccio's responses and
21 Ms. Penelow's responses.

22 THE COURT: All right. Mr. Marketos, what's the -- I
23 don't know what the objection would be to the admissibility of
24 those documents.

25 I understand the objection to the timing of it. I get

1 it. But outside of that, these are statements of a party
2 opponent, no?

3 MR. MARKETOS: They normally would be, Your Honor,
4 except that you -- that there objections to them, and I just
5 need to look -- I need to look at the issue. I mean, they're
6 just trying to enter in a bunch of interrogatory answers, and
7 that's not normally how they're used at trial. Normally you
8 would just impeach a witness with them or -- entering an
9 entire set of interrogatories is not normally how we do it
10 under the Rules of Civil Procedure.

11 So I just -- I mean, I need to look at it. And I
12 apologize.

13 THE COURT: All right. So what do we want to do
14 then, folks? Are we going to go through the rest of the jury
15 instructions and then we're going to wait for you all to
16 review these documents and then we'll get back on the record?

17 MR. WYATT: I can look at the specific
18 interrogatories we have in mind, if that will narrow this
19 issue. I think we can address the other documents in batch
20 because except for maybe one or two things, it really is all
21 guidelines or company policy documents. I don't think there
22 are going to be separate objections to individual documents.

23 THE COURT: All right. So let's skip on the
24 interrogatories for now.

25 What's the next batch then? You said it was what?

1 MR. WYATT: It was the batch that I mentioned
2 beginning D-1058 and continuing with some interruptions
3 through D-1067. Those are the guidelines, the DHHS
4 guidelines. Some of these are already in evidence. These are
5 just different years with the same --

6 THE COURT: So what years have already been admitted?

7 MR. WYATT: I'm inferring from the documents that are
8 on my list here it's 2007, 2009, 2010, and 2013 would already
9 been in evidence.

10 THE COURT: And which ones are you looking to admit?

11 MR. WYATT: 2006, 2008, 2011, 2012, and two editions
12 in --

13 THE COURT: Are they identical to the guidelines from
14 the other years?

15 MR. WYATT: I believe that there changes from one
16 edition to the next. It gets updated with new data and new
17 medicines, et cetera, over time.

18 THE COURT: Is there anything substantive -- I mean,
19 is there anything substantively different, thought, about
20 these guidelines from year to year?

21 MR. WYATT: I believe there are substantive
22 differences in the guidelines -- I can't think of an example
23 standing here, but they are --

24 THE COURT: Well, I guess what I'm trying to figure
25 out -- here's what I'm trying to get at, Mr. Wyatt. Is

1 this -- we put in a bunch of guidelines. We're missing a few
2 years, and so there's really no surprise there for the
3 Relators. Right? These guidelines are in evidence, and
4 there's just a couple of years that we're trying to fill the
5 gap, or are you trying to put something through the back door
6 that in this guideline in this particular year that we didn't
7 admit says something completely different than the guidelines
8 we've all been listening to and relying upon, and so now this
9 is a back door to get some significantly different information
10 into the trial that is not consistent with the other yearly
11 guidelines?

12 MR. WYATT: It's the former, Your Honor. We want to
13 show the jury that these are published routinely, that they
14 have guidelines --

15 THE COURT: All right. Then that's a different
16 argument.

17 Mr. Marketos, these are guidelines, several of which
18 have already been admitted. They're just moving in guidelines
19 to complete, I guess, the other years during the relevant
20 period, I presume, between 2006 and '14 or whatever it may be.

21 MR. MARKETOS: I guess, Your Honor. I guess if it's
22 supposed to be useful for closing, that's going to be
23 interesting. But if, as represented, if they are merely just
24 gap fillers, then we're not going to --

25 THE COURT: I don't have any issue either. I'm going

1 to allow those in, based upon that representation.

2 But, Mr. Wyatt, make sure that you're not arguing --
3 you are arguing something very unique about a particular
4 guideline now that I've just allowed. Mind you, it's really
5 for continuity and consistency that these guidelines have
6 existed through the relevant period.

7 MR. WYATT: Yes.

8 THE COURT: They're admitted.

9 MR. WYATT: Okay. Thank you, Your Honor.

10 And the remaining documents, it's a longer list, but
11 they are policy documents --

12 THE COURT: Janssen policy documents?

13 MR. WYATT: Yes, Your Honor.

14 THE COURT: All right. And -- well, what type of
15 policy documents?

16 MR. WYATT: They're the sort that we've seen on the
17 screen. So there were the speakers' bureau policy, for
18 example, that shows, you know, we have these criteria for the
19 speakers, we have these criteria for the substance of the
20 program, the needs assessment and so on. It's things like
21 that with respect to other topics of relevance to the case,
22 including product promotion, fair market value, advisory
23 boards. And some of these things have been referenced just in
24 testimony or shown on the screen but have just not been
25 admitted previously.

1 THE COURT: All right.

2 MR. WYATT: We also did include this list, or some of
3 them, anyway, for opening, and there was no objection to them
4 at that time.

5 THE COURT: You did?

6 MR. WYATT: Yeah. I can't represent here that it's
7 every single one, but many of these documents were in that
8 representation -- or that list that we provided the other side
9 for opening, and there were no objections.

10 THE COURT: All right.

11 MR. MARKETOS: Let me just look at it, Your Honor,
12 because, to be clear, both sides had objections to both of
13 these. We had a discussion about 8038. I keep repeating
14 myself on this issue. So I'm going to look at these documents
15 one by one. We had objections to their government documents;
16 they had objections to ours. And what we did as practice --
17 because I sent over a list at the beginning of trial, and I
18 ended up having to go one by one, as Your Honor knows, for the
19 first rather than preadmitting all these documents. Now it
20 seems like we're trying to pre-admit all of the documents that
21 they wanted to but after trial's closed. So I need to look at
22 the documents one by one.

23 THE COURT: All right. Is that something that can be
24 done now or is that something you're saying we are going to
25 have to address on the lunch break?

1 MR. MARKETOS: Yeah, it's something we're going to
2 have to address on the lunch break, Your Honor. I can't be
3 cavalier about this. This is --

4 THE COURT: All right. Mr. Wyatt, is there another
5 batch of documents or is that it?

6 MR. WYATT: That's it, Your Honor.

7 THE COURT: All right. So there are two batches of
8 documents: There are interrogatories and those policy-related
9 documents that Relators are going to review.

10 Mr. Wyatt.

11 MR. WYATT: Sorry. There is one other issue that I
12 forgot about. It's the CMS policy manual for Medicare Part D.
13 That was used in opening. That was not objected to in
14 opening. I believe it's distinct from the regulation issue
15 because it's really a policy manual; it's not a government
16 website and available for all to see. So that should be
17 admissible as well. And there was an agreement at one time
18 that there would be no objection to government documents
19 because they are admissible under 8038.

20 THE COURT: Mr. Marketos, you are aware of that
21 exhibit specifically?

22 MR. MARKETOS: Yeah, I am. If that's what that is,
23 then we're not going to object to it.

24 THE COURT: All right. That one is in. I'll allow
25 that to be admitted. So there are two batches of documents

1 that I'm going to let the Relators review, and we can deal
2 with it during lunch.

3 One is the interrogatories, and if there's something
4 more particular, then I'm going to ask you to provide that to
5 Relators' counsel in advance, to meet and confer because there
6 may be less of a concern, if they're not looking at every
7 single response. And then the other is the batch of policies.
8 Fair enough.

9 MR. WYATT: Thank you, Your Honor.

10 THE COURT: I'll reserve on those two, and then we'll
11 deal with it during the lunch break.

12 MR. WYATT: I do appreciate the Court's attention to
13 this. It was not our intent to sandbag anyone. To the
14 contrary, we gave them a list, assuming that these would not
15 be very controversial, and they just became unexpectedly
16 controversial. I do apologize for the diversion and
17 appreciate the Court's attention.

18 THE COURT: Let me ask you all this, then, for
19 purposes of use of the interrogatories, because I need to give
20 final instructions this morning, and that issue is going to be
21 pending. Can I simply say, You may hear answers that have
22 been given? Can I put a "may" in there so that we can decide
23 on this instruction? Look, if there's no interrogatories in
24 evidence, this is one of several and numerous instructions
25 that the jury is just going to ignore. But what's the

1 objection to giving some kind of --

2 MR. MARKETOS: This is part of the problem.

3 Normally, the way that you use an interrogatory at trial,
4 right, and this is part of the rule -- it's Rule 33, I
5 believe, of the Federal Rules of Civil Procedure -- is it
6 comes in as evidence may come in. So they didn't use it with
7 the Relators so that we could then cross-examine or redirect
8 with the Relators. So they're now posttrial admitting
9 interrogatory answers that the Relators have not had a chance
10 to address.

11 THE COURT: But, Mr. Marketos, the instruction simply
12 defines what an interrogatory is. I'm not putting in that
13 second paragraph that says, You may consider the
14 interrogatories.

15 MR. MARKETOS: Instruction is fine. I'm sorry, Your
16 Honor.

17 THE COURT: I'm just talking about the instruction.
18 All it's going to say is, You may have heard answers that a
19 party gave in response to written questions submitted by the
20 other side. The written questions are called interrogatories.
21 Written answers were given in writing and under oath before
22 the trial. Period, the end.

23 MR. MARKETOS: That's fine, Your Honor. I guess that
24 presupposes that the interrogatories are coming in is my
25 point.

1 THE COURT: I'm not presupposing. I'm just saying I
2 have to give the final instructions this morning. I don't
3 believe in delaying the final instructions because we have
4 these two issues pending. Why not give the instruction with
5 the "may" so it's included? If I ultimately decide that I'm
6 not going to allow these interrogatories to come in, I'm not
7 concerned about the jury getting a superfluous instruction,
8 some unnecessary instruction out of all the other instructions
9 they get. But if I do decide they are admissible and I admit
10 them, I don't have to go back and say, Members of the jury, I
11 have to give you an additional instruction on what an
12 interrogatory is.

13 MR. MARKETOS: No. No objection to the use of the
14 "may" instruction.

15 THE COURT: All right. And I'm also going to say
16 that the parties gave. I'm not even going to specify Relators
17 in this instruction. I'm going to say, You may have heard
18 answers that the parties gave in response to written questions
19 submitted -- it's basically the first paragraph of that
20 instruction only where I'm substituting "may" in the
21 beginning. And I'm going to state that the parties gave in
22 response. Any objection to that kind of general vague
23 instruction?

24 MR. MARKETOS: I don't have an objection to that,
25 Your Honor.

1 THE COURT: Mr. Wyatt.

2 MR. WYATT: No objection.

3 THE COURT: All right. So, for now, that's the
4 instruction that we're going to use for use of
5 interrogatories. With the caveat that I don't even know if
6 I'm going to allow these to be admitted, but we are going to
7 wait and see, and we'll adjust those during lunch.

8 So are we back on instructions?

9 Mr. Marketos, you're standing, but I don't know if you
10 have something else you want to say.

11 MR. MARKETOS: No, I don't, Your Honor. I apologize.

12 THE COURT: Mr. Wyatt.

13 MR. WYATT: Thank you, Your Honor.

14 So with respect to pages 26 and 27, which collectively
15 encompass our proposed Part D instruction and then the
16 instruction on the overview of Relators' claims, in the letter
17 last night on the rulemaking for Part D, one of the arguments
18 that was made in the letter is that the rulemaking is
19 inappropriate as evidence because it should be an instruction,
20 or there should be instruction on the law or something to that
21 effect. This highlights the issue that came up at sidebar,
22 which is that if we're not going to have evidence from the
23 regulation as to what CMS's thinking was about the regulation,
24 there needs to be instruction on that issue.

25 So if we're not going to have an instruction on Part D

1 along the lines of what we proposed, I would suggest that we
2 at least alter the language of Instruction 22 where we define
3 in two ways -- actually three ways.

4 So, first of all, right now it reads: Including
5 Medicare Part D and Medicaid and ADAP will cover and pay for a
6 drug if and so on. As we showed yesterday, Medicaid and ADAP
7 have their own coverage requirement. That's actually admitted
8 by one of the Relators' witnesses in this case. Medicaid and
9 ADAP are not subject, or at least not required, to follow the
10 medically accepted indication provision of the Medicare law.
11 So it would be incorrect as a matter of law to instruct the
12 jury that the coverage requirements are the same, and I would
13 submit that the burden is on the Relators to show what the
14 coverage requirements for those other entities are.

15 THE COURT: That issue has already been raised,
16 though, by you all, correct?

17 MR. WYATT: It has been.

18 THE COURT: Okay.

19 MR. WYATT: But it's been admitted by a witness at
20 trial that Medicaid has its own coverage rule.

21 THE COURT: The fact witness?

22 MR. WYATT: Yes, Your Honor.

23 THE COURT: All right. That's the transcript that
24 you showed me the other day?

25 MR. WYATT: It is.

1 THE COURT: All right.

2 MR. WYATT: The next issue is with respect to
3 medically accepted indication where it says, "which means any
4 FDA-approved use on the label that is supported by one or more
5 citations in certain drug compendia." We would propose that
6 instead we define medically accepted indication, because I'm
7 not sure where this language comes from, but it doesn't track
8 the statute or the policy manual.

9 What the policy manual says is, "Medically accepted
10 indication refers to the diagnosis or condition for which a
11 drug is being prescribed, not the dose being prescribed for
12 such indication." We think that's how the language there
13 should read.

14 THE COURT: Where would that language go?

15 MR. WYATT: Instead of "which means any FDA-approved
16 use on the label" through the end of that sentence, it should
17 say, "use for medically accepted indication," which means the
18 diagnosis --

19 THE COURT: Sorry. You got to go slower, Mr. Wyatt.

20 MR. WYATT: Sure. My mistake, Your Honor.

21 THE COURT: So where it reads, "which means any
22 FDA-approved use on the label," you want to substitute that
23 language with what?

24 MR. WYATT: "Which means the diagnosis or condition
25 for which a drug is being prescribed, not the dose being

1 prescribed for such indication."

2 THE COURT: "Diagnosis or condition."

3 MR. WYATT: "For which a drug is being prescribed,
4 not the dose being prescribed for such indication."

5 THE COURT: Let me hear from Relators.

6 MR. MARKETOS: Disagree, Your Honor. I think they're
7 trying to change the theory of the case. You don't just argue
8 that a fact witness said X. I can point to their own
9 documents that -- compliance documents that refer to the
10 opposite. I think these instructions have been how they have
11 been since the -- they were originally proposed, and we're not
12 changing the theory of the case away from the FDA-approved
13 use. That's been the entire trial.

14 THE COURT: All right.

15 MR. WYATT: I'm sorry. Do you want to hear from me
16 or not?

17 THE COURT: You have more to say?

18 MR. WYATT: It's simply there have -- the
19 instructions have not been issued previously, so this is not a
20 law --

21 THE COURT: No, no, I understand that. I understand
22 your point, and I understand Mr. Marketos's.

23 Look, I will tell you, I'm going to take a look at it,
24 but, for now, I don't intend to revisit this language, but I
25 am going to review what you raised on the record.

1 MR. WYATT: Thank you, Your Honor.

2 I would also simply propose that we add the following
3 sentence also from the manual right after the current sentence
4 that ends in "certain drug compendia," which is "Part D
5 sponsors are responsible for ensuring that coverage Part D
6 drugs are prescribed for medically accepted indications."

7 THE COURT: Mr. Marketos.

8 MR. MARKETOS: Our definition of medically accepted
9 indication, Your Honor, tracks the language of the statute,
10 and it is starting to refer to manuals now to suggest changes
11 to the legal instruction that the Court's going to give, and
12 we don't believe that's appropriate.

13 THE COURT: All right. I'm going leave the language
14 as is, but your objection is noted, Mr. Wyatt.

15 What's the next instruction?

16 MR. WYATT: So last item on this, there's language,
17 "Coverage for drugs may be excluded." And so on that
18 sentence --

19 THE COURT: Right.

20 MR. WYATT: -- under Medicare, the entity that has
21 the discretion to decide whether exclusion is appropriate on
22 this basis -- or whether to adopt that exclusionary policy, is
23 Part D plan sponsors. So you would need to have evidence in
24 this case that there was, in fact, any Part D plan sponsor
25 that has a rule that would exclude drugs that are not

1 reasonable or necessary, and no such evidence came in.

2 THE COURT: Well, then, you can argue that in
3 closing.

4 MR. WYATT: Fair enough.

5 THE COURT: All right.

6 MR. WYATT: Let's move on.

7 I appreciate that, Your Honor.

8 THE COURT: By the way, Mr. Wyatt, do we need to get
9 into this FDA regulation as well at some point?

10 MR. WYATT: I'm going to have one proposal for that,
11 for FDA.

12 THE COURT: No, I'm talking about the letter you all
13 submitted with the 300-some-page --

14 MR. WYATT: Yes.

15 THE COURT: -- where there's comments from third
16 parties and --

17 MR. WYATT: Yes, Your Honor. But I'll move quickly.
18 There's only a couple of other issues.

19 THE COURT: All right. Go ahead.

20 MS. BROWN: So the next one is 23.3, which is on
21 page 32.

22 THE COURT: Right.

23 MR. WYATT: And here I just want to clarify -- the
24 Court's already ruled, but I just want to clarify that as the
25 Court knows, we believe *Greenfield's* wrongly decided, but even

1 if it's not, it doesn't apply to the 2006 to 2010 time period.
2 And I'm not sure it was completely clear in our prior
3 submissions that that was a point we wanted to make in the
4 jury instructions, but it is.

5 And so we would propose that this instruction, if it's
6 going to state *Greenfield's* rule, which I understand the Court
7 is bound by it, would only apply to 2010 to 2014.

8 MR. RUSS: Your Honor, I'm not sure that's accurate.
9 It varies circuit to circuit in case law. There are cases
10 that hold that that same test applied before there was a
11 change in the law -- or the amendment to the AKS. So without
12 any cases to review from Mr. Wyatt, I'm not sure that that's
13 accurate from a retrospective point of view.

14 MR. WYATT: So I rely on *Greenfield* for that
15 proposition, Your Honor.

16 THE COURT: Basically look at when the decision came
17 out?

18 MR. WYATT: Yeah. Well, so *Greenfield* came out in
19 2018, but what it's referring to is that the AKS was amended
20 in 2010. And what it says is that "It was part of an overall
21 effort to strengthen whistleblower actions based on medical
22 care or kickbacks, and the legislative history of the
23 provision does not explain the term 'resulting from,' but the
24 congressional record indicates it was enacted to avert legal
25 challenges that sometimes defeat legitimate enforcement

1 efforts."

2 So it's definitely a change in the law in the Third
3 Circuit's view, one that changed the legal standard or --

4 THE COURT: So you think there's two separate
5 standards that apply to the third element depending on what
6 year we're talking about?

7 MR. WYATT: Correct.

8 THE COURT: Was that proposed in Janssen's initial
9 proposal?

10 MR. WYATT: That was -- it was part of our trial
11 brief. What I'm not remembering is whether the proposal's in
12 the instructions. Our proposal was simply to have a but-for
13 instruction on this issue.

14 THE COURT: Right.

15 MR. WYATT: And so the sub-argument of that is --

16 THE COURT: At least give us that for --

17 MR. WYATT: Yes.

18 THE COURT: -- 2006 to 2009 or whatever it may be?

19 MR. WYATT: Yes.

20 THE COURT: Let me hear from Mr. Russ.

21 MR. RUSS: Your Honor, I would need to go back and
22 look at the case law, but I know there's case law -- and I
23 can't remember if it's in the Third Circuit or not -- that
24 says the AKS amendment just clarifies the law. It didn't
25 change it. And so -- and that varies from circuit to circuit.

1 And if memory serves, when this came up in the trial
2 brief, I believe there was a Third Circuit case --

3 THE COURT: Well, when do you plan on looking at that
4 since I'm instructing the jury today?

5 MR. RUSS: I can look as quickly as possible.

6 THE COURT: All right. Do that. For now, I'm going
7 to keep the language as is, but I want to hear from Mr. Russ
8 so that -- I'm going to reserve on that, but for now I'm not
9 changing it.

10 What's the next one?

11 MR. WYATT: So quickly on materiality, which is on
12 page 33 -- I'm sorry. That's not right. Give me a minute.

13 (Brief pause.)

14 MR. WYATT: Page 46.

15 THE COURT: Okay.

16 MR. WYATT: We would propose additional language to
17 materiality to one more sentence. "A false claim is not
18 material to the government's payment decision if the
19 government would have paid the claims with full knowledge of
20 the alleged noncompliance." That's almost straight out of
21 *Petratos*, and I think the concern I have is that if we're just
22 reading this statutory language, we're sort of setting the
23 jury up to be applying the wrong -- or misunderstanding the
24 materiality requirement sort of in the same way that the
25 Supreme Court clarified what materiality meant in *Escobar*.

1 It really is very general to say it has a natural
2 tendency to influence, and I think the effect on the payment
3 decision is a really important clarification of what the
4 materiality standard means.

5 THE COURT: And so the proposed language that
6 you're -- just say it a little bit slower. The proposed
7 language you're looking at at the end of that instruction for
8 24.18 is what?

9 MR. WYATT: That's correct. It would be "A false
10 claim is not material to the government's payment decision if
11 the government would have paid the claims with full knowledge
12 of the alleged noncompliance."

13 THE COURT: All right.

14 Mr. Russ?

15 MR. RUSS: Your Honor, this comes up in all of our
16 False Claims Act cases, and the other courts that we proposed
17 instructions for have followed exactly this, the statutory
18 language of materiality that is in the statute.

19 I understand that there's case law on every single
20 element, that you could go and pick and choose language to try
21 to help your side or, you know, hurt the other side. But that
22 is the statutory definition of material or materiality in the
23 False Claims Act.

24 THE COURT: All right. I mean, I think I -- there's
25 a few circumstances where I've reviewed the proposed

1 instructions where I did not add additional language with
2 respect to definitions that were already defined in the
3 statute. So I'm going leave this instruction as is, because I
4 think that's consistent with how I ruled on other proposed
5 instructions, not just with materiality but other terms, by
6 not adding -- and I'm not going to use the term "cherry-pick"
7 -- but not adding selective language from different cases to
8 augment the description. Otherwise, we might be here for
9 weeks.

10 So I'm going to leave it as is, but I note the
11 objection.

12 MR. WYATT: Understood, Your Honor. Just two more.

13 On page 51, the FDA approval instruction.

14 THE COURT: Yes.

15 MR. WYATT: We would request an addition of "or
16 disapproved" after "approved" in the last sentence, just to
17 balance this out.

18 I previously expressed a concern that this instruction
19 could be read to say, "Disregard Dr. Patel's testimony." And
20 I think adding "or disapproved" doesn't change the meaning of
21 the instruction but does give it greater balance.

22 THE COURT: Hold on one second. One second.

23 (Brief pause.)

24 THE COURT: Well, Mr. Wyatt, before I even hear from
25 Mr. Marketos -- Mr. Marketos, are you objecting?

1 MR. MARKETOS: Yes, Your Honor.

2 THE COURT: All right. Then hold on.

3 Mr. Wyatt, here's my concern about that. Okay?

4 MR. WYATT: Yeah.

5 THE COURT: It changes the meaning of that final
6 statement that I struggled with in this instruction. By the
7 way, this is a much lighter instruction than the one Relators
8 proposed to the Court.

9 But here it says, "I am instructing you that there is
10 no statute or regulation that says that the FDA's silence
11 means that it has approved a promotional advertising
12 commission."

13 If I add the words "or disapproved," then it almost
14 defeats the entire point of this instruction and that last
15 sentence. It's basically saying, FDA silence means that
16 whatever you're doing is okay because that's not a
17 disapproval. So I'm concerned about changing the meaning of
18 that final statement.

19 I think it's much softer language, and I think that's
20 even the term Mr. Marketos used when I proposed this revised
21 instruction that the Relators gave to me, but let me hear from
22 Mr. Marketos.

23 MR. MARKETOS: Your Honor, obviously, we believe the
24 law is that the -- but based on the regulations themselves and
25 case law, that the FDA silence is affirmatively not approval.

1 It must be in writing to be approval as the regulation states.

2 So when Your Honor gave us this instruction to begin
3 with, it was a very -- very nice compromise for Janssen, from
4 our point of view. What's the point of saying "approve" or
5 "disapprove" at the end of the day? That's basically --

6 THE COURT: Yeah, I agree. I think it changes the
7 meaning of what I'm intending to say there.

8 So I'm going to leave the instruction as is. I mean,
9 Janssen's objection is noted.

10 Relators' objection is also noted, that you want the
11 language to be much more definitive. But in my review of the
12 law, I was not comfortable instructing as definitively on that
13 particular issue in light of the testimony that came out
14 during trial, at least with Dr. Patel. And I was more
15 comfortable -- I will say I am comfortable instructing that
16 there's no statute or regulation that says that the FDA
17 silence means that it has approved a promotional advertising
18 submission.

19 So that's a compromise that I can see. I understand
20 that this is one that neither party agrees with, but that's --
21 the instruction is going to stay as is.

22 Mr. Wyatt, where are we going next?

23 MR. WYATT: Last one, Your Honor, and thank you.

24 Page 57, the damages that parties may recover
25 instruction. The last sentences says, "In determining the

1 amount of the damages that the United States and states are
2 entitled to, you are not to consider the possibility Relators
3 share recovery." I have a concern that the jury will perceive
4 that they are not to consider that at all for any purpose, and
5 so we would suggest adding "You may, however, consider the
6 possibility the Relators share recovery in evaluating the
7 bias, credibility or motive of the Relators." And we did
8 supply an example of an instruction given in another case.
9 Didn't track that verbatim but essentially say -- said the
10 same thing.

11 THE COURT: I remember this issue. So I will tell
12 you, the reason -- well, here's how I tried to address it,
13 Mr. Wyatt. You have a credibility-of-witness instruction that
14 encompasses that point that you want to make, and you're able
15 to argue about credibility with this.

16 The reason why I thought I protected that concern that
17 Janssen has, I said, "In determining the amount of the
18 damages." It's very specific that with respect to that
19 determination, you're not to consider the recovery of the
20 Relators.

21 Let me hear from Mr. Russ, though. I know you were
22 standing up.

23 But I appreciated Janssen's concern there. This
24 language was very particular, and I tried to keep it limited
25 to determining the amount of the damages. But I also want to

1 make clear that under no circumstances can they not address
2 those issues with respect to credibility of a Relator or a
3 witness. That's a separate instruction.

4 And, by the way, it does talk about different factors
5 to be considered for credibility. One of them is, you know,
6 some financial incentive in the case or motive or bias.

7 So I think -- let me hear from Mr. Russ. I don't want
8 to speak for the Relators, but I thought those concerns were
9 addressed.

10 MR. RUSS: No, you know it, Your Honor. The
11 credibility issues don't belong in this damages calculation
12 instruction. I think it's perfect as written. There would be
13 no reason for, in a damage instruction, for them to consider
14 the credibility of particular witnesses, particularly when
15 there's a concern that they may deduct from the government's
16 recovery because there's a potential for Relators --

17 THE COURT: Yeah. And, Mr. Wyatt -- and here's the
18 one other point I'll make, Mr. Wyatt. If I add that language
19 that you want me to add in this instruction, I end up
20 highlighting and giving attention to the jury to say, let me
21 do this a second time. You know, I understand that you could
22 consider the Relators' credibility with this issue once, but
23 now I'm going to give them a second instruction when it comes
24 to damages. Like, are you sure you don't want to consider
25 their credibility with respect to their recovery? And I feel

1 like that tips the scale and is basically almost me implying
2 to the jury that they really need to consider that issue for
3 purposes of credibility.

4 That's not the Court's purview. I'm not going to tell
5 them what issues to deal with or what not to deal with with a
6 particular witness. So I'm going keep the language as is, but
7 I appreciate the objection. I will tell you, though, I did
8 consider that objection heavily in drafting the language, and
9 I understand you all want that additional language added, but
10 I'm going to keep it as is.

11 MR. WYATT: Understood, Your Honor. Those are the
12 only specific points I wanted to call out, in addition to the
13 ones we've already put on the record.

14 THE COURT: All right. So I -- with respect to the
15 jury instructions, have I addressed all the objections on the
16 record here? Other than your prior objections that you have
17 preserved for all time.

18 MR. RUSS: For Relators, yeah, Your Honor.

19 MR. WYATT: Yes, Your Honor.

20 THE COURT: So that's separate and apart. I
21 appreciate you all going through that pretty efficiently.

22 The use of interrogatories, we decided, will be
23 included for now with that tempered language a bit.

24 What's next? Should we talk about this FDA regulation,
25 or do you want to deal with that at lunch with the remaining

1 documents that you all have to review?

2 MR. MARKETOS: Yes, Your Honor. That would be my
3 preference, if we could, because I got a lot to go through.

4 THE COURT: All right. So why don't we do this,
5 folks. We are going to give -- I'm going to take a few
6 minutes. We're going to have a recess. I need to make sure
7 the final instructions are actually done consistent with what
8 we just discussed. I'll have some printouts for you all, or
9 do you want them emailed to you? How do you want this done,
10 folks?

11 MR. WYATT: Printout would be great, Your Honor.

12 THE COURT: I'll have a printout for me, because I
13 usually read off of paper. When I'm doing the instructions,
14 you'll have a printout. That way you all can just kind of go
15 along with what I'm going to be reading to the jury. And then
16 during lunch, I think I'm going to give the jurors an hour
17 break. You will not have an hour, because we need to address
18 these evidentiary issues and I need those tacked down.

19 MR. WYATT: And the verdict form at lunch as well?

20 THE COURT: Have you guys had an opportunity to even
21 really review the verdict sheet? I don't know. Do you guys
22 want to talk about that now? It's not extensive. I mean,
23 it's more condensed -- it's a hybrid. It's more condensed
24 than Janssen's proposal, but it's more than what you all
25 proposed from the Relators' side. Do you want to take a look

1 at it? And I think one of the substantive changes --
2 primarily, I went with the format for Relators except for the
3 state claims. I thought just saying, hey, folks, what do you
4 think about these state claims was insufficient for a verdict
5 form. I think you have to break down these states.

6 So if you look at what I've done, I've taken Janssen's
7 proposal, or at least some hybrid of their proposal, when it
8 comes to the state claims, because the instructions -- let me
9 say this. Let me strike that.

10 The verdict sheet has to be consistent with the
11 instructions that I'm giving. And the way I'm instructing the
12 jury on the state claims is they have to assess the damages
13 for each of these states. So how do I give them that type of
14 an instruction and then the verdict sheet doesn't reflect the
15 very instruction that I'm giving for purposes of damages? I
16 don't know if you all want to take a look at it now and talk
17 about it or you want to add this to the lunch break. We need
18 to finalize this verdict sheet. What I attempted to do is --
19 I'll be candid. I thought Janssen's verdict sheet was just
20 unbelievably confusing for the jury. So I condensed it. I
21 thought the Relators' version was more clear, but I thought
22 Janssen was correct on you have to expand on these state
23 claims. The jury has to be able to allocute these damages
24 appropriately. They can't just bundle them up and say, by the
25 way, here's the damages. Figure it out later.

1 So if you look at the verdict sheet, that's the hybrid
2 that I proposed to both parties.

3 But I don't know if you all need some time to discuss
4 internally or we can talk about it now.

5 MR. RUSS: Your Honor, I think it would be helpful
6 for us to discuss, potentially meet and confer with Janssen on
7 this. It would be helpful for us to kind of lock this down
8 before we give a closing argument or we are going to walk the
9 jurors through the verdict sheet.

10 THE COURT: Well, then, here's my point. You guys
11 close before lunch.

12 MR. RUSS: Right.

13 THE COURT: Don't you all need to work on that issue
14 now? Do you want to take some time now, and I just give you
15 guys a 15-minute recess? But, I mean, I plan to give
16 instructions, and Relators will close, then we break for
17 lunch, and then Janssen will close. Then we'll break shortly
18 for the rebuttal.

19 MR. RUSS: I think we take some time now, Your Honor.

20 THE COURT: All right. Why don't we do this. We're
21 in a -- let's say 15-minute recess. Do what you need to do
22 personally, and why don't you meet and confer on the verdict
23 sheet, and I'll come back on, and I'll inform the jurors that
24 I'm dealing with some legal issues. I'll take responsibility
25 for that. I don't think they're going to be too concerned.

1 They know they're getting instructions today. They know
2 closing arguments are coming today. I'm sure that they're
3 anxiously anticipating kind of getting to that point. So I'll
4 let them know we have some issues to resolve.

5 With that, folks, we are in recess for 15 minutes.
6 Please use some of that time to deal with the verdict sheet
7 and confer. I'll come back in. We're in recess. You all may
8 be seated.

9 MR. RUSS: Thank you, Your Honor.

10 MR. WYATT: Thank you, Your Honor.

11 MR. MARKETOS: Thanks, Your Honor.

12 (A short recess occurred.)

13 THE DEPUTY COURT CLERK: Please remain seated.

14 THE COURT: Folks, you guys have at least a hard copy
15 of the instructions?

16 MS. BROWN: Yes, thank you.

17 THE COURT: All right. The final instruction, I only
18 give that right before deliberation after closing, so that's
19 the version that I'm going to give. I don't think there's
20 going to be any real dispute there, but take a look at that,
21 and we can address it at lunch, if there's a concern, but that
22 instruction, to me, does not make sense to do four hours
23 before they get the case. So I always reserve that final
24 instruction for after all the closings and rebuttal. Right
25 before I send them in, that's the instruction I give that

1 reminds them about the basics of what they're supposed to do,
2 including picking a foreperson. You guys can review that.
3 We'll address it at lunch if there's a concern, after you guys
4 break for lunch, and then we'll go from there.

5 Folks, anything we need to discuss before I bring out
6 the jurors to just read these instructions?

7 MR. RUSS: Yes, Your Honor. On the verdict sheet,
8 we've conferred. I think Mr. Wyatt has some different
9 concerns. So let me level-set on these -- these are difficult
10 verdict sheets because there's a lot of overlap.

11 THE COURT: Right.

12 MR. RUSS: So under the federal False Claims Act, we
13 could go for the -- all Medicaid money and get what's called
14 FMAP portion back for the United States, and that's set by
15 statute. Then there's a state portion that is going to be --
16 we have been in touch with main NAMFCU coordinator which is
17 the National Medicaid Fraud Control Unit coordinator, to get
18 the state portions of the 27 -- or 26 states plus the District
19 of Columbia.

20 So we are trying to make this streamlined so that we
21 are not overlapping. So, for instance, all the claims at
22 issue that are federal claims and Medicaid claims will be in
23 the false claims for both the first question and then later in
24 the later questions, so there's some overlap. So we are
25 trying to figure out how to best apportion this so we don't

1 have the jury answering questions, you know, that are
2 overlapping on the number of claims --

3 THE COURT: Right. I get that.

4 MR. RUSS: So --

5 THE COURT: Is there a proposal that you guys have?

6 MR. RUSS: One way that I think it would work, Your
7 Honor -- and there's a couple different ways we could do it,
8 because the way that Your Honor -- I think it's appropriate
9 and correct on Instruction Number 25 -- has written that if
10 you find a violation of the federal False Claims Act, right,
11 for either the AKS or the off-label marketing portion, you
12 must also find that Janssen violated the analogous provisions
13 of all the state False Claims Acts. What that would mean is
14 there would be a bunch of yeses down the page for all the
15 states. And so one way we could do it is to streamline these
16 into basically two questions, right, or two sets of questions,
17 the off-label marketing and then the kickbacks, because the
18 number of claims would be the same and the number of -- which
19 is for penalties, and then the damages would then be
20 apportioned amongst the many plaintiffs if we were to get that
21 verdict and ultimately get that judgment.

22 That streamline, it takes out about six or seven pages
23 of the verdict sheet.

24 THE COURT: Right. Okay. That's your proposal?

25 MR. RUSS: Yes, Your Honor. I think that would be

1 the easiest way.

2 THE COURT: Okay. Let me hear from Mr. Wyatt.

3 MR. WYATT: We oppose that, Your Honor. I mean, the
4 reason that this is being brought up is because the Relators
5 needed to put in state-specific evidence for the damages and
6 they didn't do it. So you can't get around that by saying,
7 well, actually, it's all just federal damages now because
8 Medicaid is a federal program. There's a federal share that
9 maybe the federal government can go after under the FCA, but
10 then there's state shares, which is why we have 26 state
11 plaintiffs and the District of Columbia in this case. Those
12 have to be litigated, if at all, under the state False Claims
13 Act claims.

14 By the way, this verdict form was submitted jointly by
15 the parties. There was variation on language, but there was
16 no disagreement that there would be separate blanks and
17 answers for the states. That was part of both parties'
18 submissions.

19 So this is changing because they don't like the way the
20 evidence came in or they made a strategic decision not to put
21 it in this way. But you can't do it this way --

22 THE COURT: So I don't have it before me.

23 Mr. Russ, is that accurate, that this was part of the
24 joint proposal?

25 MR. RUSS: We actually proposed two different ones,

1 Your Honor. Originally, we did propose one that didn't
2 have -- so the AKS is somewhat different --

3 THE COURT: What's confusing about my hybrid? I'm
4 just trying to figure out -- what is the problem with how I
5 identified it?

6 MR. RUSS: So we do have Medicaid claims. We have
7 Medicaid damages. Professor Shaked testified at length about
8 the Medicaid, the FMAP -- the FMAP is part of the
9 United States' damages because it's a federal grant. So we
10 have that information. What I think they're -- trying to
11 avoid is this sort of 27 -- list of duplicative questions for
12 the number of claims in that if you find a violation of the
13 federal False Claims Act, that same money, you got and go and
14 click yes to each of these and then apportion the amounts.
15 That's one of the reasons that we proposed, for the Medicaid
16 money, which is the non-FMAP portion of Medicaid, that it be
17 apportioned to the states because they are all working
18 together with the NAMFCU, and then if we get that judgment,
19 it's our verdict to hold on to, we can go back to the states
20 and say, here's your portion.

21 THE COURT: Do you have -- I guess -- do I have
22 something before me that would show me what this proposed
23 revision would look like? I'm hearing the words that you're
24 saying, but I can't visualize the verdict form.

25 MR. RUSS: Sure. It would -- I can find it very

1 quickly, Your Honor. It would be the same first...

2 THE COURT: By the way, Mr. Wyatt, I'll hear from
3 you. I'm not saying I'm going to approve it, but I also --
4 it's hard for me to address this in a vacuum without seeing
5 what it actually looks like.

6 So, Mr. Russ, are you going to be able to put that
7 together?

8 MR. RUSS: I think we can put that together very
9 quickly, Your Honor.

10 THE COURT: Why don't we do that.

11 And, Mr. Wyatt, I know you're objecting to it, but is
12 there something else that you're proposing for me to put
13 together that's different than mine, or are you saying mine
14 would be acceptable? You're opposing this revised version of
15 what I provided to you all?

16 MR. WYATT: I do want to make one record on one
17 thing, but yes. To your question, yes. I'm fine with the
18 Court's proposal, subject to objections that we don't need to
19 get into because it relates to --

20 THE COURT: All right. What's the additional thing
21 that you wanted to mention?

22 MR. WYATT: So two things. I just want to respond to
23 one thing that was said a second ago by counsel, which is that
24 it follows as a matter of course if the jury finds a federal
25 violation that there are also state violations.

1 We just argued this. And I believe the resolution was
2 we can argue to the jury that they failed to establish the
3 Medicaid coverage requirements for the states. So it does not
4 follow that if there's a federal False Claims Act violation
5 that there are state False Claims Act violations. Those are
6 separate questions, and it's part of why they have to be
7 separately broken up on the verdict form.

8 The only other thing I just want to mention -- and so
9 we filed a different verdict form. Those are all on the
10 record. I'm not going to reargue any of that. Those would
11 just be the version that we have proposed, but, otherwise, I
12 have no issues with this verdict form.

13 The only point of information I will make is that
14 there's no separate question on this verdict form for ADAP.
15 And so I believe that means ADAP questions are not going to
16 the jury. I know counsel for Relators disagrees with that,
17 but I did want to flag that for the Court.

18 THE COURT: Let me hear from Mr. Russ on that.

19 MR. RUSS: Yeah. So a couple things, Your Honor. On
20 Instruction Number 25, it very clearly says, "If you find
21 Janssen liable under standards explained earlier in the False
22 Claims Act as to any Medicaid reimbursements in a particular
23 state, then you should find that Janssen is also liable under
24 that state law."

25 So we have this overlap because this is Medicaid money

1 which is mostly federal money. Nothing in the way that we
2 have written these questions limits it to Medicare Part D.
3 That's what Janssen proposed. They proposed that you have to
4 limit it to the type of money, Medicare or ADAP. That's not
5 the way the law works.

6 We have the FMAP portion of Medicaid payments. We have
7 federal grant money in ADAP, and we have all the Medicare
8 Part D money. All that goes back to the United States.

9 Then we've got a smaller portion, which is about -- and
10 this is -- you know, we have record evidence of this --
11 it's -- it's the state portion -- the Medicaid money in this
12 case is about 17 percent. So the state portion of that is
13 going to be somewhere around 8 percent. So that 8 percent is
14 very easily taken, and saying, If you find that they violated
15 the federal False Claims Act, here's the money to put in this
16 bucket rather than going down each of the states.

17 And I'm not sure I'm aware of any requirement that you
18 have to go through each state and apportion that money when
19 they are co-plaintiffs trying to get the same bucket of
20 damages.

21 THE COURT: All right. Let me see your proposed
22 revision. Why don't you guys take some time to do that. How
23 long is that going to take?

24 MR. RUSS: 15 minutes, Your Honor.

25 THE COURT: All right. I'll be back in 15 minutes.

1 We're in recess.

2 (A short recess occurred.)

3 THE COURT: Off the record.

4 (Discussion was held off the record.)

5 THE COURT: And, folks, we're back on the record, and
6 then I'll hear from both sides.

7 I've reviewed the revised verdict form from Relators.
8 I'm inclined to approve that verdict form for purposes of the
9 case. But I have some concerns about how the state law claims
10 were presented during this trial, and I'm reserving on that
11 decision because I have allowed Janssen to file a Rule 50
12 motion.

13 One of the bases of that motion that they've already
14 laid on the record is the deficiency of evidence with respect
15 to the state law claims. And so I want to make sure that
16 Relators are on notice that if there is a verdict of liability
17 on those state claims, by no means are you covered by the fact
18 that I've approved this verdict sheet. If anything, you might
19 have actually caused yourself a greater issue because you've
20 condensed this verdict sheet, where you're not allowing the
21 jurors to allocate damages to each state, and you're not
22 allowing them to make a determination as to the number of
23 false claims per state. You're not even allowing them to
24 determine the number of false claims for the states as a
25 group. And that's how the verdict form is shown.

1 So Mr. Russ, I just want to be clear about that, that
2 don't take my acceptance of the verdict sheet as my acceptance
3 that the evidence is not deficient. I'm going to review that
4 issue when it's been fully briefed by the parties, because I
5 anticipate if there's a liability verdict on any claim, but
6 especially the state claims, chances are you raised on the
7 record that they intend to file that motion.

8 Are we clear?

9 MR. RUSS: I am clear, Your Honor. One thing I just
10 want to put on the record is we think that this streamlines it
11 because of the overlap. Right? So any claim under the False
12 Claims Act for a Medicaid state program, that's going to be
13 captured by the numbers of claims in Questions 1 and 4.
14 Right?

15 THE COURT: Right, which is in there. You're right.
16 You do identify the number of claims early on in the verdict
17 form when it comes to those claims.

18 MR. RUSS: Right, Your Honor. And so that's there;
19 that's in the record. That's in the evidence. And so I
20 understand Your Honor to be saying as to the apportionment of
21 the state portion that we're going to put into a bucket
22 that -- because, look, in any nationwide case, you're going to
23 have maybe sometimes upwards of 50 states. Of course it would
24 be to the defendants' benefit to go through and --

25 THE COURT: But you're saying that you presented

1 evidence that the jury could allocate damages for each state
2 and identify the number of false claims for each state.

3 MR. RUSS: We have the percentage breakdown for
4 Medicaid payments in Janssen's own documents.

5 THE COURT: But if they're able to do that, why keep
6 it out of the verdict form?

7 MR. RUSS: Why keep the breakdown? Because we
8 don't -- my position is, and our position is, you don't have
9 to when you have a group of plaintiffs that are sharing in
10 that recovery.

11 THE COURT: All right. Let me hear from Mr. Wyatt,
12 but you know where I'm inclined to go. But let me hear from
13 you and make sure you make your record.

14 MR. WYATT: I appreciate that, Your Honor, and part
15 of what Your Honor said captures our position so I won't
16 reiterate all that.

17 But one question I -- or one issue I will raise is on
18 further review of the form -- and I read it quickly earlier
19 when we were off the record. It's in Track Changes so I
20 missed this, but there's an additional issue, which is there's
21 no separate liability form for yes, no, you know, You violated
22 the this state law, FCA.

23 I understand Relators' position is it follows as a
24 matter of course that if the jury finds a False Claims Act
25 violation under the federal statute, so, too, must they under

1 the state statutes. But that's just not true for the reasons
2 we've discussed.

3 And I don't read Instruction 25 to say that. What
4 Instruction 25 says is, I have given you the principles that
5 govern your determination of the elements of falsity,
6 causation, materiality, et cetera. But you still have to
7 evaluate that under each state's law.

8 And I don't even think it's -- or maybe it's still
9 disputed, but if it is, it's just wrong -- that states have
10 different coverage requirements and -- I mean, we'll set this
11 out in Rule 50, but this is true; that the states have
12 different coverage requirements than the federal government.
13 So you can't --

14 THE COURT: So you're saying that they should still
15 be making a determination -- the question should still exist
16 in the state claims verdict sheet.

17 MR. WYATT: At least the liability question should.

18 THE COURT: Mr. Russ, why isn't that added there? I
19 don't have it before me now. Do I need to grab it or do you
20 have it?

21 MR. RUSS: The instruction, Your Honor?

22 THE COURT: No. The verdict form.

23 MR. RUSS: So because of the instruction, Your Honor.
24 The way we've adapted the verdict form is consistent with the
25 instruction that if you find earlier in the False Claims Act

1 to any Medicaid reimbursement, Medicaid specifically -- that's
2 all we're talking about -- in a particular state when we have
3 that claims data -- and that's been presented -- then you
4 should find that Janssen is also liable under the state's law.

5 And so we're taking the state law violations if they --
6 if they find that there's a violation of the federal False
7 Claims Act as to the Medicaid reimbursement.

8 THE COURT: I'm just trying to think about some
9 analogy here. I've seen verdict forms where even when
10 something is included in another claim, they're still asked
11 the question, Mr. Russ.

12 And by the way, that might be a problem if we had
13 what's considered an inconsistent verdict, where they found,
14 you know, for one or the other.

15 But I don't see why we wouldn't propose the question.
16 I don't know if I've ever seen a verdict form that says, you
17 don't even have to answer the question as to the state claims.
18 Because you said "yes" to this, we're not even going to ask
19 you on a completely separate claim "yes" or "no." I still
20 think that should be there.

21 I mean, I understand that -- I don't think that's
22 inconsistent with the instructions, but I don't see how you
23 have state claims where you don't even ask them to make a
24 determination about liability and you automatically presume it
25 within a verdict sheet. I'm not comfortable with that. And I

1 think that objection from Mr. Wyatt -- I mean, I tend to agree
2 with.

3 I'm okay with the condensed version, and I'll live with
4 that verdict form for the jury. Like I said, if there are
5 issues with that posttrial, we'll address it in briefing in
6 the Rule 50 motion. But why wouldn't you -- I think you
7 should ask the question of liability to every claim you have
8 in the case, including the state claims. And if the
9 instruction is there, you'll make sure to remind the jurors
10 and argue the jury instructions. But I'm not going to
11 preclude asking them about liability to an entire claim in the
12 case just because the argument is, Well, of course if they
13 found liability here, they must find it here. I still believe
14 that we have to ask the question.

15 MR. RUSS: So would the proposal be, Your Honor, list
16 out the states -- the 26 states and District of Columbia, yes
17 or no, did you find liability under the --

18 THE COURT: Well, I don't even know if we needed to
19 do that. I thought your condensed version has all the states
20 together.

21 MR. WYATT: It does. We can certainly do that. I
22 think that would be fine.

23 THE COURT: I mean, I thought you opposed breaking
24 the states separately, yes or no.

25 MR. WYATT: Yeah, I think that that's -- I don't

1 think that's required. And so if we want to group together
2 the liability question, I think that's a great idea,
3 Your Honor.

4 THE COURT: I don't have the hard copy before me, but
5 I think Mr. Wyatt -- I agree with Janssen. You're going to
6 have to ask the liability question on the state claims at bare
7 minimum. It can't be presumed in the verdict sheet simply
8 because the argument from -- you're all going to make and from
9 the instructions that it flows that they would find liability
10 in A, which means they have to find liability in C and
11 therefore we're not going to ask you the question.

12 I think the jurors have to be asked to make a
13 determination by the evidentiary standard that there's
14 liability on each of these claims.

15 MR. WYATT: And I think that's fine, Your Honor. And
16 to be clear, certainly not trying to get around any sort of
17 liability finding. It's the two buckets, the same claims that
18 will be false under the False Claims Act that might be false
19 under the state, and then under state law, the state's, if you
20 get a Medicaid --

21 THE COURT: I understand that. You'll make that
22 argument in closing, and I'm comfortable with that.

23 What about breaking down the states for "yes" or "no"
24 versus all the states collectively?

25 MR. RUSS: So all the states listed "yes" or "no" as

1 you find them, and then a question not as to the number of
2 claims but just the number of damages.

3 THE COURT: I presume that -- right. I mean, that's
4 still consistent with what you've proposed but it's a little
5 more elaborate than the last version.

6 MR. RUSS: I think that protects us, Your Honor, so
7 I'm happy to have those questions for liability in the --

8 THE COURT: So, Mr. Wyatt, that only addresses some
9 of your objection, but I am going to make that change to the
10 verdict sheet. All right? I know that doesn't answer all of
11 your concerns, but it does a little bit on at least making the
12 jury get asked about liability and have that question
13 responded to.

14 MR. RUSS: Agree with that, Your Honor, and just one
15 more point for the record. I don't think it requires further
16 discussion, but there was a representation made so I want to
17 address it, about NAMFCU and the states can just split it all
18 up.

19 That would absolutely have to be in the record. Either
20 we would have to have somebody from NAMFCU here, we would have
21 to have somebody from the states -- they're not the states.

22 THE COURT: All right. But that argument is going to
23 be --

24 MR. KLEIN: But that's a Rule 50 issue.

25 THE COURT: That's an argument for another day. I

1 think we made it clear that this issue is going to be
2 revisited at that point, but, for now, we have the verdict
3 form done. So here's what I'm going to do. I don't want to
4 delay the jury anymore. That verdict sheet should be revised
5 consistent with our discussion so I have it during the lunch
6 break to review, because I don't need the verdict sheet, now
7 that we finalized it, handed to the jury. They even haven't
8 had closing arguments. So I don't want to delay the jurors
9 anymore. I presume Relators are going to -- Counsel, you're
10 going to revise that verdict sheet consistent with what we
11 just discussed, with liability being asked on the state claims
12 and the yes and no for each state, and then, I guess, there's
13 no specific identification of false claims for each state.
14 That's not going to be there but there's damages.

15 MR. RUSS: Right, because the false claims will
16 overlap --

17 THE COURT: I got it.

18 MR. RUSS: Let me just confer with my team and make
19 sure everybody is okay with the proposal.

20 (Brief pause.)

21 MR. RUSS: I feel like we're delaying things. I take
22 blame for that, Your Honor. Can we have time just to get the
23 verdict sheet into our slides for the closing argument as the
24 Court has just...

25 THE COURT: Yes. Why don't I do the instructions and

1 then take the break. I'd like to get these instructions done
2 and wake up this jury. They've been waiting. I'm going to
3 take a break after the instructions. They are going to need
4 it after I go through all these anyway. You all might need a
5 break. So how about during that break, you all have a little
6 bit of time now that you understand what the final verdict
7 sheet is going to be. And I'll also ask you, while I'm giving
8 the instructions, because I'm just reading these off of the
9 same document you all have, maybe you work -- have somebody
10 work on the verdict sheet while I'm reading the instructions.

11 MR. RUSS: We'll do it, Your Honor.

12 THE COURT: Anything else we need to address before I
13 have the jurors in here for the final instructions?

14 MR. WYATT: Only one clarification for the record and
15 the court reporter. NAMFCU, all caps, N-A-M-F-C-U.

16 THE COURT: Okay. I appreciate that. Megan does,
17 too.

18 One other issue, I want to highlight it now. This
19 monitor is out, folks. Do we need that revised for the
20 closing arguments? That could be an issue for the jurors. As
21 you know, half the jury looks at that screen and the other
22 half looks at the one on my left.

23 Does that need to be fixed for the Relators' closing?

24 MR. MARKETOS: Yes, for sure.

25 THE COURT: All right. So, Kim, we are going to need

1 someone to work on that.

2 I'm not going to deal with that now. I don't have
3 displays or demonstratives for final instructions. So we will
4 deal with that on the break. But I want to alert you all that
5 that's an issue.

6 I guess, Ms. Brown, is that a concern for you as well?

7 MS. BROWN: It is, Your Honor.

8 THE COURT: All right. Kim, you'll work on it?

9 Thank you.

10 Why don't we get the jurors in first, though, so I can
11 give these final instructions. Then we'll take a break to
12 work on the technical issues and give Relators' counsel a
13 little bit of time.

14 But, Mr. Russ, you are going to work on the verdict
15 sheet, correct?

16 MR. RUSS: I'm working on it right now, Your Honor.

17 THE COURT: Make sure that you share it with
18 Janssen's counsel so I'm not dealing with that issue.

19 THE DEPUTY COURT CLERK: All rise.

20 (Jury enters the courtroom.)

21 THE COURT: Folks, everybody have a seat. Members of
22 the jury, welcome back. I apologize for the delay. As I said
23 to you earlier, today I'm going to give final instructions. I
24 needed to work on those a bit. I apologize for the delay this
25 morning. But I'm going to give you final instructions. We're

1 going to take a short break because it's lengthy, and then
2 we'll deal with closing arguments. We also have a technical
3 issue with one of the monitors that we are going to work on
4 during that break.

5 You can see, maybe, this monitor is out. We need this
6 monitor to be able to work for some of you who rely upon this
7 monitor more than that one, so we are going to work on that
8 for the closing arguments.

9 But let me just remind you. So there are 28
10 instructions, so get comfortable. There are subparts to some
11 of these instructions. So it's going to take me some time to
12 read these on the record to you all. This is similar to the
13 outset. These instructions, some of these, are going to be
14 similar to what I instructed you at the beginning of the
15 trial. Some of them are going to be repeated instructions,
16 what I gave you during the trial, and some of these
17 instructions you have not heard before. They're final
18 instructions that are added in for these final instructions.

19 As I said before, pay attention, be mindful of the
20 instructions I'm giving you, but you will have a few written
21 copies of these instructions verbatim with you in
22 deliberations. So to the extent you need to refer to these
23 instructions or remember something that I told you in these
24 final instructions, you're going to have them with you, and
25 there will be a table of contents also to help guide you if

1 there's a particular instruction that you all wanted to look
2 at.

3 With that, like I said, 28 instructions. You'll know
4 when you're coming to the end, but some of them have subparts,
5 so it's a little tricky. Technically, that's more than 28.

6 So with that, I'll give you the final instructions, and
7 then we'll take a break before we begin with closing
8 arguments. I know there's a little bit of a delay, so we
9 ordered the lunch a little bit later so that we can
10 accommodate that not sitting around.

11 Instruction Number 1, Introduction and Role of Jury.

12 Now that all the evidence has been presented, I will
13 instruct you on the law, and then the attorneys will present
14 to you closing arguments to summarize and interpret the
15 evidence in a way that is helpful to their clients' positions.
16 As with opening statements, closing arguments are not
17 evidence. After that, you will retire to the jury room to
18 deliberate on your verdict in this case. You will decide what
19 the facts are and then apply those facts to the law that I
20 will give to you. You and only you will be the judges of the
21 facts. You will have to decide what happened. I play no part
22 in judging the facts. You should not take anything I might
23 have said or did during the trial, or anything else I may say
24 or do, as indicating what I think of the evidence or what your
25 verdict should be. My role is to be the judge of the law. I

1 make whatever legal decisions have to be made during the
2 course of the trial, and I'll explain to you the legal
3 principles that must guide you in your decisions. You must
4 follow that law whether you agree with it or not.

5 Instruction Number 2, Summary of the Case.

6 I'm going to give you the instruction number so that
7 when you hear 27, you all know that you are coming to an end.

8 Instruction Number 2, Summary of the Case.

9 This case is brought under a federal law called the
10 False Claims Act. Additionally, this case is brought under
11 similar laws in 26 states and the District of Columbia, each
12 of which have their own version of the False Claims Act.
13 Individuals who bring a lawsuit on behalf of the government
14 under a False Claims Act are called "Relators." In order for
15 a private citizen to bring claims under the False Claims Act,
16 the private citizen must disclose his or her allegations to
17 the Department of Justice. The private citizen, known as the
18 Relator, may then pursue his or her claims in federal court.
19 The Department of Justice is not involved in this case for the
20 purposes of this trial.

21 In this lawsuit, Relators Jessica Penelow and Christine
22 Brancaccio claim Defendant Janssen Products -- I'll identify
23 them as Janssen -- violated federal and state False Claims
24 Acts by knowingly causing materially false claims for
25 reimbursement of two HIV medicines, Prezista and Intelence, to

1 be submitted to three government programs: Medicare,
2 Medicaid, and the AIDS Drug Assistance Program, referred to as
3 ADAP.

4 Relators allege that from 2006 to 2014, Janssen engaged
5 in off-label marketing and kickback schemes related to
6 Prezista and Intelence. With regard to off-label marketing,
7 Relators allege that Janssen unlawfully marketed, one,
8 Prezista as being lipid neutral, lipid friendly, or as having
9 a similar impact on lipids as the competitor drug Reyataz,
10 which Relators claim was false; two, Prezista as being
11 suitable for treatment-naive patients before the FDA approved
12 it for treatment-naive patients; three, Intelence as being
13 suitable for once-a-day dosing when it was only approved for
14 twice-a-day dosing; and, four, Intelence as being suitable for
15 treatment-naive patients when it was only approved for
16 treatment-experienced patients.

17 Relators allege that these uses were contrary to the
18 drugs' FDA-approved labels and/or not medically necessary and
19 reasonable.

20 Regarding kickbacks, Relators allege that Janssen paid
21 prescribers to serve on a speaker program and paid for
22 prescribers' travel, meals, and hotel stays in order to induce
23 them to prescribe its drugs Prezista and Intelence and/or to
24 reward them for doing so.

25 Janssen denies these allegations. Janssen states that

1 the claims submitted to the government for reimbursement of
2 Prezista and Intelence were appropriate, its sales
3 representatives properly promoted Prezista and Intelence to
4 doctors, and that it properly used speaker programs to educate
5 doctors about Prezista, Intelence, and HIV-related issues.
6 Janssen further states its actions did not influence
7 physicians to improperly prescribe Prezista and Intelence and
8 were not material to the government's reimbursement of these
9 medicines.

10 Instruction Number 3, Conduct of Jury.

11 Now a few words about your conduct as jurors. First, I
12 did instruct you that during the trial and until you have
13 heard all the evidence and have retired to the jury room to
14 deliberate, you are not to discuss the case with anyone. Not
15 even among yourselves. If anyone should try to talk to you
16 about the case, including a fellow juror, bring it to my
17 attention promptly.

18 There are good reasons for this ban on discussions, but
19 most importantly, the need for you to keep an open mind
20 throughout the presentation of evidence.

21 I know that many of you use cell phones, smart phones
22 and other portable electronic devices, laptops, notebooks and
23 other computers, both portable and fixed, and other tools of
24 technology to access the internet and to communicate with
25 others. You also must not talk to anyone about this case or

1 use these tools to communicate electronically with anyone
2 about the case.

3 This includes your family and friends. You may not
4 communicate orally with anyone about the case on your cell
5 phone, smart phone or portable or fixed computer or device of
6 any kind, or use these devices to communicate electronically
7 by messages or postings of any kind, including email, instant
8 messages, text messages, text or instant messaging services
9 such as Twitter, or through any blog, website, internet chat
10 room or by way of any other social networking websites or
11 services, including Facebook, LinkedIn, and YouTube.

12 If any lawyer, party, or witness does not speak to you
13 when you pass in the hallway, ride the elevators, or the like,
14 remember it's because they are not supposed to talk or visit
15 with you either. That is why you are asked to we're your
16 juror tags that show that you are someone who is not to be
17 approached in any way.

18 Second, do not read or listen to anything related to
19 this case that is not admitted into evidence. By that I mean
20 if there's a newspaper article or radio or a television report
21 relating to this case, do not read the article or watch or
22 listen to the report. In addition, do not try to do any
23 independent research or investigation on your own on matters
24 relating to the case or this type of case.

25 Do not do any research on the internet, for example.

1 You are to decide the case upon the evidence presented at
2 trial. In other words, you should not consult dictionaries or
3 reference materials, search the internet, websites, blogs, or
4 use any other electronic tools to obtain information about
5 this case or to help you decide the case. Please do not try
6 to find out information from any source outside the confines
7 of this courtroom.

8 Again, do not reach any conclusion on the claims or
9 defenses until all the evidence is in -- which it is in, but
10 you're not going to deliberate yet. You're still waiting for
11 closing arguments. Keep an open mind until you start your
12 deliberations at the end of the case.

13 Instruction Number 4. Bench conferences.

14 During the trial, it was necessary for me to talk with
15 the lawyers out of your hearing by having bench conferences,
16 or you may have heard the term "sidebar," which means the same
17 thing. We are not trying to keep important information from
18 you. Those conferences were necessary for me to fulfill my
19 responsibility, which is to be sure that evidence is presented
20 to you correctly under the law. I may not have granted an
21 attorney's request for a conference. Do not consider my
22 granting or denying a request for a conference as any
23 indication of my opinion of the case or of what your verdict
24 should be.

25 Instruction Number 5. Evidence.

1 The evidence from which you are to find the facts
2 consists of the following:

- 3 1. The testimony of the witnesses; and,
4 2. Documents and other things received as exhibits.

5 The following things are not evidence:

- 6 1. Statements, arguments, and questions of the lawyers
7 for the parties in this case;
8 2. Objections by lawyers;
9 3. Any testimony I tell you to disregard; and,
10 4. Anything you may see or hear about this case
11 outside the courtroom.

12 You must make your decision based only on the evidence
13 that you see and hear in court. Do not let rumors,
14 suspicions, or anything else that you may see or hear outside
15 of court influence your decision in any way.

16 You should use your common sense in weighing the
17 evidence. Consider it in light of your everyday experience
18 with people and events, and give it whatever weight you
19 believe it deserves. If your experience tells you that
20 certain evidence reasonably leads to a conclusion, you are
21 free to reach that conclusion.

22 There are rules that control what can be received into
23 evidence. When a lawyer asked a question or offered an
24 exhibit into evidence, and a lawyer on the other side thought
25 that it was not permitted by the rules of evidence, that

1 lawyer may have objected. This simply means that the lawyer
2 requested that I make a decision on a particular rule of
3 evidence. You should not be influenced by the fact that an
4 objection was made. Objections to questions are not evidence.

5 Lawyers have an obligation to their clients to make
6 objections when they believe that evidence being offered is
7 improper under the rules of evidence. You should not be
8 influenced by the objection or by the Court's ruling on it.
9 If the objection was sustained, ignore the question. If it
10 was overruled, treat the answer like any other. If you were
11 instructed that some item of evidence is received for a
12 limited purpose only, you must follow that instruction.

13 Also, certain testimony or other evidence was ordered
14 struck from the record, and you are instructed to disregard
15 that evidence. Do not consider any testimony or other
16 evidence that got struck or excluded. Do not speculate about
17 what a witness might have said or what an exhibit might have
18 shown.

19 Instruction Number 6. Direct and Circumstantial
20 Evidence.

21 There are two types of evidence that you may use in
22 reaching your verdict. One type of evidence is called "direct
23 evidence." An example of direct evidence is when a witness
24 testifies about something that that witness knows through his
25 or her own senses, something the witness has seen, felt,

1 touched, or heard or did. If a witness testified that he saw
2 it raining outside and you believed him, that would be direct
3 evidence that it was raining. Another form of direct evidence
4 is an exhibit where the fact to be proved is its existence or
5 current condition.

6 The other type of evidence is called "circumstantial
7 evidence." Circumstantial evidence is proof of one or more
8 facts from which you can infer another fact. If someone
9 walked into the courtroom wearing a raincoat covered with
10 drops of water and carrying a wet umbrella, that would be
11 circumstantial evidence from which you could conclude that it
12 was raining.

13 You should consider both types of evidence that are
14 presented to you. The law makes no distinction in the weight
15 to be given to either direct or circumstantial evidence. You
16 are to decide how much weight to give any evidence.

17 Instruction Number 7. Credibility of Witnesses.

18 In deciding what the facts are, you may have to decide
19 what testimony you believe and what testimony you do not
20 believe. You are the sole judges of the credibility of the
21 witnesses. Credibility means whether a witness is worthy of
22 belief. You may believe everything a witness says or only
23 part of it or none of it. In deciding what to believe, you
24 may consider a number of factors, including the following:

25 1. The opportunity and ability of the witness to see

1 or hear or know the things the witness testifies to;

2 2. The quality of the witness's understanding and
3 memory;

4 3. The witness's manner while testifying;

5 4. Whether the witness has an interest in the outcome
6 of the case or any motive, bias, or prejudice;

7 5. Whether the witness is contradicted by anything the
8 witness said or wrote before trial or by other evidence;

9 6. How reasonable the witness's testimony is when
10 considered in the light of other evidence that you believe;
11 and,

12 7. Any other factors that bear on believability.

13 The weight of the evidence to prove a fact does not
14 necessarily depend on the number of witnesses who testified.
15 What is more important is how believable the witnesses were
16 and how much weight you think their testimony deserves.

17 Instruction Number 8. Preponderance of the Evidence.

18 This is a civil case. Relators are the parties who
19 brought this lawsuit. Janssen is the party against which the
20 lawsuit was filed. Relators have the burden of proving their
21 case by what is called a "preponderance of the evidence."
22 That means that Relators have to prove to you, in light of all
23 the evidence, that what they claim is more likely so than not
24 so.

25 To say it differently, if you were to put the evidence

1 favorable to Relators and the evidence favorable to Janssen on
2 opposite sides of the scales, Relators would have to make the
3 scales tip somewhat on their side. If Relators fail to meet
4 this burden, the verdict must be for Janssen. If you find,
5 after considering all the evidence, that a claim or fact is
6 more likely so than not so, then the claim or fact has been
7 proved by a preponderance of the evidence.

8 In determining whether any fact has been proved by a
9 preponderance of evidence in the case, you may, unless
10 otherwise instructed, consider the testimony of all witnesses,
11 regardless of who may have called them, and all exhibits
12 received in evidence, regardless of who may have produced
13 them.

14 You may have heard of the term "proof beyond a
15 reasonable doubt." That is a stricter standard of proof, and
16 it applies only to criminal cases. It does not apply in civil
17 cases such as this, so you should put it out of your mind.

18 Instruction Number 9. Use of Deposition.

19 A deposition is a sworn testimony of a witness taken
20 before trial. The witness is placed under oath and swears to
21 tell the truth, and lawyers for each party may ask questions.
22 A court reporter is present and records the questions and
23 answers.

24 Instruction Number 10. Use of Interrogatories.

25 You may have heard answers that a party gave in

1 response to written questions submitted by the other side.

2 The written questions are called "interrogatories." The
3 written answers were given in writing and under oath before
4 the trial.

5 Instruction Number 11. Use of Requests for Admission.

6 Evidence was presented to you in the form of admissions
7 to the truth of certain facts. These admissions were given in
8 writing before the trial in response to requests that were
9 submitted under established court procedures. You must treat
10 these facts as having been proved.

11 Instruction Number 12. Charts and Summaries in
12 Evidence.

13 The parties have presented exhibits in the form of
14 charts and summaries. I decided to admit these charts and
15 summaries in place of the underlying documents that they
16 represent in order to save time and avoid unnecessary
17 inconvenience. You should consider these charts and summaries
18 as you would any other evidence.

19 Instruction Number 13. Charts and Summaries Not
20 Admitted in Evidence.

21 Certain charts and summaries that have not been
22 received in evidence have been shown to you in order to help
23 explain or illustrate the contents of books, records,
24 documents, testimony, or other evidence in the case. For
25 example, you may see charts and summaries during the parties'

1 opening and closing statements or during the testimony of
2 opinion witnesses. Unless the charts or summaries were
3 specifically admitted as trial exhibits, they are not
4 themselves proof of any facts. They are not binding on you in
5 any way. If they do not correctly reflect the facts shown by
6 the evidence in the case, you should disregard these charts
7 and summaries and determine the facts from the evidence.

8 Instruction Number 14. Opinion Testimony.

9 You've heard testimony containing opinions from expert
10 witnesses. In weighing this opinion testimony, you may
11 consider their qualifications, the reasons for their opinions,
12 and the reliability of the information supporting those
13 opinions, as well as the factors I've previously mentioned for
14 weighing the testimony of any other witness. The opinions of
15 the expert witnesses should receive whatever weight and
16 credit, if any, you think appropriate, given all the other
17 evidence in the case.

18 In deciding whether to accept or rely upon the opinions
19 of the expert witnesses, you may consider any bias that they
20 may have, including any bias that may arise from evidence that
21 they have been or will be paid for reviewing the case and
22 testifying or from evidence that the expert witnesses testify
23 regularly and make a large portion of their income from
24 testifying in court.

25 Instruction Number 15. Transcript of Audio-Recorded

1 Conversation.

2 You've heard conversations that were recorded. This is
3 proper evidence for you to consider. You have seen
4 transcripts of some recordings to help you identify speakers
5 and as a guide to help you listen to the recordings.

6 If you believe at any point that the transcript said
7 something different from what you heard on the recording,
8 remember, it is the recording that is the evidence, not the
9 transcript. If at any time there was a variation between the
10 recording and the transcript, you must be guided solely by
11 what you heard on the recording and not by what you saw in the
12 transcript.

13 Instruction Number 16. Corporate Responsibility.

14 The defendant, Janssen, is a corporation. The
15 corporation is a legal entity that may act only through
16 individuals who are called its agents. The agents of a
17 corporation are its officers, directors, employees, and other
18 persons who are authorized by the corporation to act for it.
19 You must give to a corporate defendant the same impartial
20 consideration of the evidence that you would give to any
21 individual.

22 The legal responsibility of a corporation, if any, is
23 based on the conduct of its agents. To find Janssen liable
24 under the False Claims Act, you will need to find that the
25 Relators proved by a preponderance of the evidence that the

1 elements of each claim are satisfied through the acts or
2 omissions of officers, directors, employees, or other agents
3 of Janssen; that such agents performed such acts within the
4 course and scope of his or her employment; and that such acts
5 or omissions were intended for the benefit of the corporation.

6 Instruction Number 17, Overview of Relators' Claims.

7 In this case, Relators seek recovery from Janssen under
8 the federal and state False Claims Acts. Relators allege that
9 Janssen is liable under the False Claims Acts due to its
10 alleged off-label marketing. Relators allege that Janssen is
11 liable under the False Claims Acts due to alleged violations
12 of the Anti-Kickback Statute. Relators allege that Janssen
13 caused submission of false claims in multiple independent
14 ways.

15 First, the claim is false if it is ineligible for
16 reimbursement under a federal health care program. In
17 determining whether a claim is eligible for reimbursement, you
18 must consider that federal health care programs, including
19 Medicare Part D, Medicaid, and ADAP, will cover and pay for a
20 drug that is used for a "medically accepted indication," which
21 means any FDA-approved use on the label that is supported by
22 one or more citations in certain drug compendia. Coverage for
23 drugs may also be excluded if they are not reasonable and
24 necessary for the diagnosis or treatment of illness or injury.

25 Second, a claim is also false if Janssen violated the

1 Anti-Kickback Statute in connection with the claim.

2 I will now explain the elements of the Anti-Kickback
3 Statute.

4 Instruction Number 18, Anti-Kickback Claims.

5 I instruct you that any claim submitted to a federal
6 health care program resulting from a violation of the
7 Anti-Kickback Statute is a false claim under the False Claims
8 Act. Therefore, for the kickback claims, in determining
9 whether Janssen violated the False Claims Act, you will first
10 have to determine whether Janssen violated the Anti-Kickback
11 Statute. For you to find that Janssen violated the
12 Anti-Kickback Statute, Relators must prove each of the
13 following elements by a preponderance of the evidence: First,
14 that Janssen offered or paid any remuneration, including any
15 kickback or bribe, directly or indirectly, openly or secretly,
16 in cash or in kind.

17 Second, that one purpose of the remuneration offered or
18 paid was to induce or reward prescriptions of Prezista or
19 Intelence.

20 Third, that claims for payment for those prescriptions
21 were submitted to a federal health care program and there was
22 some evidence in this case of a link between the alleged
23 inducement and the claims submitted for reimbursement.

24 And, fourth, that Janssen acted knowingly and
25 willfully.

1 I will now provide you with further explanation of each
2 of these elements.

3 Instruction 18.1, Anti-Kickback Claims. Elements:
4 Remuneration.

5 The first element of the Anti-Kickback Statute that
6 Relators must prove by a preponderance of the evidence is that
7 Janssen offered or paid remuneration. Remuneration means the
8 transfer of anything of value from one person or entity to
9 another person or entity. Remuneration can be direct or
10 indirect, overt or covert, in cash or can include anything of
11 value in any form whatsoever.

12 Instruction 18.2, Anti-Kickback Claims. Elements:
13 Inducement.

14 The second element of the Anti-Kickback Statute that
15 Relators must prove by a preponderance of the evidence is that
16 one of the purposes of the remuneration was to induce or
17 reward the referral, purchase, order, recommendation of any
18 item or service paid for by a federal health care program. It
19 is not a defense that there might have been some other reason
20 for the remuneration if you find by a preponderance of the
21 evidence that one of the purposes of the remuneration was to
22 induce or reward the referral, purchase, order, recommendation
23 of any item or service to be paid for by the federal health
24 care program. Unlawful inducement does not need to be the
25 primary purpose of the remuneration.

1 Instruction Number 18.3, Anti-Kickback Claims.

2 Elements: Federal Health Care Program.

3 The third element of the Anti-Kickback Statute that
4 Relators must prove by a preponderance of the evidence is that
5 claims for payment for those prescriptions were submitted to a
6 federal health care program and that there was some evidence
7 in this case of a link between the alleged inducement and the
8 claims submitted for reimbursement. The term "federal health
9 care program" means any plan or program that provides health
10 benefits and is funded entirely or indirectly by the
11 United States Government. I instruct you that Medicare,
12 Medicaid, and ADAP are federal health care programs.

13 Instruction Number 18.4, Anti-Kickback Claims.

14 Elements: Knowledge and Willfulness.

15 The fourth element of the Anti-Kickback Statute that
16 Relator must prove by a preponderance of the evidence is that
17 Janssen acted knowingly and willfully.

18 Instruction Number 18.5, Anti-Kickback Claims.

19 Elements: Knowledge.

20 An act is done unknowingly for purposes of the
21 Anti-Kickback Statute if the act is done voluntarily and
22 intentionally and not because of a mistake or accident.

23 Instruction Number 18.6, Anti-Kickback Claims.

24 Elements: Willfulness.

25 The term "willfully" means acting with a purpose to

1 disobey or disregard the law. An act is done willfully if
2 Janssen knew that the act was unjustifiable or wrong, even if
3 Janssen was not aware of the specific law or rule that they
4 may have been violating. Relators do not have to prove that
5 Janssen specifically intended to violate the Anti-Kickback
6 Statute.

7 Instruction 19, False Claims Act. Elements.

8 As explained earlier, Relators allege that Janssen is
9 liable under the federal False Claims Act stemming from its
10 alleged off-label marketing and stemming from its alleged
11 violations of the Anti-Kickback Statute. Therefore, the next
12 thing you have to consider is whether Janssen is liable under
13 the False Claims Act.

14 For you to find that Janssen is liable under the
15 federal False Claims Act, Relators must prove the following
16 elements by a preponderance of the evidence: One, the
17 falsity; two, causation; three, scienter, which means culpable
18 state of mind; and, four, materiality.

19 I will now explain each of these elements in turn.

20 Instruction Number 19.1, False Claims Act. Elements:
21 Falsity.

22 First, Relators must prove by a preponderance of the
23 evidence that the claims submitted or caused to be submitted
24 by Janssen were false. I have instructed you that a claim
25 resulting from a violation of the Anti-Kickback Statute is

1 false. I've also instructed you that a claim made to a health
2 care program is false if it seeks reimbursement for a
3 prescription that is not eligible for reimbursement.

4 Instruction 19.2, False Claims Act. Elements:
5 Causation.

6 Second, Relators must prove by a preponderance of the
7 evidence that Janssen caused the claims to be submitted to the
8 government. Janssen's conduct may be found to have caused a
9 submission of a claim for Medicare, Medicaid, or ADAP
10 reimbursement if, one, the conduct was a substantial factor in
11 inducing providers to submit claims for reimbursement; and,
12 two, the submission of claims for reimbursement was reasonably
13 foreseeable or anticipated as a natural consequence of
14 Janssen's conduct.

15 Instruction 19.3, False Claims Act Knowledge --
16 Elements: Knowledge.

17 Third, Relators must prove by a preponderance of the
18 evidence that Janssen acted knowingly. Knowingly means that
19 Janssen has actual knowledge, acted with deliberate ignorance
20 to the truth or falsity of their statements, or recklessly
21 disregarded the truth or falsity of the information. Relators
22 are not required to show proof of specific intents to defraud.

23 Instruction 19.4, False Claims Act. Elements:
24 Materiality.

25 Fourth, Relators must prove by a preponderance of the

1 evidence that Janssen's alleged Anti-Kickback Statute or
2 off-label marketing violations were material to the
3 government's payment decision. Material means that it had a
4 natural tendency to influence or was capable of influencing
5 the payment or receipt of money or property.

6 Instruction Number 20, Corporate Integrity Agreements
7 and Settlement Agreements.

8 You have heard testimony that Janssen was subject to
9 two Corporate Integrity Agreements in 2010 and 2013 as well as
10 Settlement Agreements in 2010 and 2013 with the federal
11 government. The Corporate Integrity Agreements and Settlement
12 Agreements were related to the resolution of allegations
13 brought by the government concerning alleged off-label
14 marketing of different products and alleged kickbacks paid
15 through speaker programs related to different products. These
16 different products did not include Prezista and Intelence.

17 This evidence of the Corporate Integrity Agreements and
18 Settlement Agreements was admitted only for limited purposes.
19 You may consider this evidences only for the purpose of
20 deciding whether, one, Janssen acted knowingly or willfully
21 regarding the conduct alleged by Relators; two, Janssen had
22 the motive or opportunity to engage in the conduct alleged by
23 Relators; three, Janssen acted with a method of operation as
24 evidenced by a unique pattern regarding the conduct alleged by
25 Relators; four, Janssen's conduct was not a mistake, an

1 accident, or impossibility; five, Janssen's conduct was not
2 made in good faith; and, six, the government would deem the
3 conduct alleged in this case to be material in deciding
4 whether to reimburse claims for Prezista and Intelence.

5 You may also consider whether the existence and terms
6 of the Corporate Integrity Agreements and Settlement
7 Agreements contradict the testimony of a witness in assessing
8 the credibility of that witness. Do not consider this
9 evidence for any other purpose. Of course, it is for you to
10 determine whether you believe this evidence and, if you do
11 believe it, whether you accept it for the purpose offered.
12 You may give it such weight as you feel it deserves but only
13 for the limited purposes that I described to you.

14 There are no claims at issue in this lawsuit regarding
15 the alleged other acts that resulted in the Corporate
16 Integrity Agreements or Settlement Agreements. You may not
17 consider the Corporate Integrity Agreements or the Settlement
18 Agreements as a substitute for proof that Janssen engaged in
19 the conduct alleged in this case. Specifically, you may not
20 use this evidence to conclude that, because there were
21 allegations of off-label marketing and kickbacks paid through
22 speaker programs with respect to other products, Janssen must
23 have engaged in the conduct alleged in this case.

24 Instruction Number 21, Withheld Documents.

25 During the course of this trial, it was discovered that

1 Janssen withheld documents that were responsive to Relators'
2 discovery requests and which Janssen was obligated to turn
3 over well in advance of the trial. Specifically, Janssen
4 withheld documents pertaining to allegations of another
5 Janssen employee, Joanne Cesario, concerning Janssen's
6 off-label promotion of Prezista and Intelence. You are
7 permitted but not required to infer that Janssen withheld this
8 evidence because it was unfavorable to Janssen.

9 Instruction Number 22, FDA Approval.

10 You have heard testimony from a Janssen employee,
11 Dr. Amit Patel, about the FDA's silence in response to certain
12 of Janssen's promotional advertising submissions regarding
13 Prezista and lipids. You also heard him testify that Janssen
14 considered the FDA's silence in response to those advertising
15 submissions as the FDA's indirect or tacit approval of
16 Janssen's advertising. I am instructing you that there is no
17 statute or regulation that says that the FDA's silence means
18 that it has approved a promotional advertising submission.

19 Instruction Number 23. State Law Claims.

20 In addition to the federal False Claims Act, Relators
21 also assert claims on behalf of the States of New Jersey,
22 California, Colorado, Connecticut, Delaware, Florida, Georgia,
23 Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts,
24 Michigan, Minnesota, Montana, Nevada, New Mexico, New York,
25 North Carolina, Oklahoma, Rhode Island, Tennessee, Texas,

1 Virginia, Washington, and the District of Columbia under their
2 versions of the False Claims Act. These State False Claims
3 Acts allow Relators like Ms. Penelow and Ms. Brancaccio to
4 bring a lawsuit on behalf of a state government.

5 Earlier I gave you instructions about the law
6 applicable to the federal False Claims Act and Anti-Kickback
7 Statute. Those instructions apply to the states' claims as
8 well. Each of the states operates a Medicaid program with
9 state and federal funds. As a result, the Anti-Kickback
10 Statute is one of the laws that is applicable to these
11 Medicaid programs.

12 Most States' False Claims Act are modeled on the
13 federal False Claims Act and have very similar or identical
14 provisions. These state False Claims Acts impose liability on
15 a defendant that knowingly presents or causes to be presented
16 a false or fraudulent claim for payment. Therefore, if after
17 following my earlier instructions you found that Janssen
18 violated the federal False Claims Act, you must also find that
19 Janssen violated the analogous provisions of all the states'
20 False Claims Acts, except I will provide separate instructions
21 for Texas.

22 Accordingly, if you find Janssen liable under the
23 standards explained earlier for the False Claims Act as to any
24 Medicaid reimbursements in a particular state other than
25 Texas, then you should find that Janssen is also liable under

1 the state's law. Conversely, if you find that Janssen is not
2 liable under the False Claims Act for any Medicaid
3 reimbursements in a particular state, then you should find
4 that Janssen is not liable under that state's law.

5 Instruction Number 24. Texas False Claims Act.

6 For Texas, you should follow the instructions I gave in
7 connection with the federal False Claims Act except as
8 modified by the instructions I now give you.

9 Janssen is liable under the Texas False Claims Act if
10 you find that, by a preponderance of the evidence, Relators
11 established that Janssen knowingly violated the Texas
12 Anti-Kickback Statute law. Texas Anti-Kickback law makes it
13 illegal to offer or pay, directly or indirectly, in cash or in
14 kind, to induce a person to refer an individual to another
15 person for the furnishing of or for arranging the furnishing
16 of any item or service for which payment may be made, in whole
17 or in part, under the Medical Assistance Program. The term
18 "knowingly" as used in the Texas False Claims Act means that
19 the defendant:

- 20 1. Had knowledge of the information;
- 21 2. Acted with conscious indifference to the truth or
22 falsity of the information; or,
- 23 3. Acted in reckless disregard of the truth or falsity
24 of the information.

25 Instruction Number 25. Damages. Overview.

1 If you find that Janssen violated the False Claims Act
2 or its state analog, then you must determine damages resulting
3 from the violation.

4 I will now explain the law related to damages.

5 However, the fact that I am instructing you on the
6 issue of damages should not be taken to mean that I have any
7 view on whether you should find liability. If you do not find
8 Janssen liable, then you should not assess any damages.

9 Relators must prove the government's damages with
10 reasonable certainty. You may not award damages that are
11 speculative, that is, damages that might be possible but are
12 based solely on guesswork. Relators are not required to prove
13 the exact amount of damages, but Relators must show sufficient
14 facts and circumstances to permit you to make a reasonable
15 estimate of the damages.

16 Instruction Number 26. Damages. Measure of Damages.

17 The measure of damages under the False Claims Act is
18 the amount of money that the government paid out by reason of
19 the false claims. If you find that Janssen submitted false
20 claims or caused false claims to be submitted to a federal
21 health care program during the damages period, then the full
22 amount paid by the government as a result of those false
23 claims is the amount of damages.

24 To account for the various state analogs to the False
25 Claims Act, you must differentiate between damages suffered by

1 the United States, the 26 states, and the District of
2 Columbia. Accordingly, the verdict form will ask you to
3 specify the amount of damages, if any, that you attribute to
4 the United States, the 26 states and the District of Columbia.

5 Instruction Number 27. Damages - Parties That Recover.

6 Any amount recovered under the federal False Claims Act
7 or the state analogs goes to the union states and the states.

8 I'm sorry. Goes to the United States. I don't know
9 what I just did there, folks. This is -- are we getting
10 towards the end? We're almost at 28. I don't know what the
11 union states were there.

12 Let me read that again.

13 Any money recovered under the federal False Claims Act
14 or the state analogs goes to the United States and the states.
15 The United States and the states may then provide the Relators
16 with a portion of that recovery. In determining the amount of
17 damages that the United States and the states are entitled to,
18 you are not to consider the possibility of a Relators' share
19 of the recovery.

20 Instruction Number 28. Number of False Claims.

21 If you find that Janssen violated the False Claims Act,
22 then you must also identify the number of false or fraudulent
23 claims that were submitted to the United States, the states,
24 and the District of Columbia. Again, the fact that I am
25 instructing you on the issue of the number of false claims

1 should not be taken to mean that I have any view on whether
2 you should find liability. If you do not find Janssen liable
3 under the False Claims Act, then you should not assess the
4 number of false claims.

5 Folks, I appreciate your patience. Those are the final
6 instructions. And I know there's a lot in there and some of
7 it was repetitive, but it's important that you get all these
8 final instructions collectively at the end of the trial. Be
9 mindful, you'll have a few written copies. I'm not going to
10 bring you eight, but you'll have a few that you can share
11 amongst yourselves in deliberations.

12 What I'd like to do is, before we get into closing
13 arguments, I need to take a short break, and then hopefully
14 you'll need one, too, just to ensure that the technology is
15 working and to give counsel a few moments to just prepare.

16 So with that, I'm going to temporarily excuse the
17 jurors back to the jury room, and we're going to address those
18 issues before bringing them back.

19 THE DEPUTY COURT CLERK: All rise.

20 (The jury exited the courtroom.)

21 THE COURT: Everybody have a seat.

22 Just two things based on the reading of the jury
23 instructions that I think need to be tweaked for purposes of
24 the written instructions that are going to go back to the
25 jury, but before I address those, does anybody else have a

1 concern about the instructions I read other than what's
2 already been raised?

3 MR. RUSS: No, Your Honor.

4 THE COURT: All right. Ms. Brown -- or Mr. Wyatt?

5 MR. WYATT: Nothing beyond what we discussed,
6 Your Honor.

7 THE COURT: They're minor. One is the title of the
8 Corporate Integrity Agreements and settlement agreement. I
9 made it plural for Settlement Agreements everywhere in the
10 instruction, but the title says, "Settlement Agreement." So
11 that's an easy fix. I'm going to correct it to say
12 "Agreements" in the title.

13 Any objection to that?

14 MR. RUSS: No objection, Your Honor.

15 MR. WYATT: No, Your Honor.

16 THE COURT: All right. Then my second one, just to
17 be consistent with the verdict sheet -- and just bear with me.
18 I have to go back now. I wasn't able to identify it while
19 reading it, but it has to do with identifying the number of
20 claims for each state.

21 Just bear with me.

22 (Brief pause.)

23 THE COURT: Was there an instruction that talked
24 about identifying the number of false claims? And maybe it's
25 in my memory, but I thought that that instruction needed to be

1 slightly tweaked before we give it to them in written form.

2 But maybe this is my imagination.

3 MR. WYATT: Well, it's 28, Your Honor, is the number
4 of false claims.

5 THE COURT: Oh, sorry.

6 So this is what I just wanted to ask you folks, right,
7 because the verdict sheet as we've discussed that's going to
8 be finalized does not, I believe, require the jurors to
9 identify the number of false claims for each state.

10 Is that correct?

11 MR. WYATT: That's correct, Your Honor.

12 THE COURT: So I don't mind that I read this. I
13 didn't think there was a need to correct it, but what I'd like
14 to do is, I'm looking at the first paragraph of Instruction
15 Number 28. And what it says there, "If you find that Janssen
16 violated the False Claims Act, then you must also identify the
17 number of false or fraudulent claims that were submitted to
18 the United States, the states, and the District of Columbia."

19 I think to be consistent with the verdict sheet, that's
20 not exactly what they're doing there. So is there a proposed
21 revision just to that language?

22 MR. RUSS: It should just be to the United States.

23 THE COURT: Yeah. With a period, correct?

24 MR. RUSS: That's right.

25 THE COURT: Look, I understand the objections to

1 Janssen on the verdict form, but I also want this in written
2 form to be consistent with the verdict sheet.

3 Any objection to the consistency revision?

4 MR. WYATT: I agree consistency is right, Your Honor.
5 I just want to -- and I think we confirmed this just now, but
6 they're not asking for findings on the number of false claims
7 for the states.

8 Is that correct?

9 MR. RUSS: That's correct, Your Honor.

10 THE COURT: My understanding is that proposed form is
11 going to have a "yes" or "no," to one of your objections,
12 Mr. Wyatt, which is they should be asked about liability for
13 each of the state claims. So every state will be identified
14 as "yes" and "no," and then let me just make sure about this.
15 Then it's just going to have a damages amount.

16 MR. RUSS: It will have a damages amount, Your Honor,
17 and I said in -- one thing I want to clarify for the record,
18 just in case it's not clear, the claims that are to the states
19 for Medicaid are claims to the --

20 THE COURT: Yeah, I know. I know that's the
21 position. They're identifying the number of false claims, but
22 that's earlier in the verdict sheet. It's not in the state
23 law claim part of it.

24 So -- and I just want to be clear, every state will be
25 listed with "yes" or "no" as to liability, and then there is a

1 group number of false claims for all those states. So that's
2 just completely omitted. It's just going to have damages.

3 MR. MARKETOS: That's correct, Your Honor.

4 THE COURT: All right. So --

5 MR. WYATT: Yeah. I mean, just for absolute clarity,
6 in the earlier part of the form, there is a blank for number
7 of claims. Those are the number of claims submitted to
8 Medicare. So the -- if there are claims that they want to do
9 something with in connection with Medicaid, under the state
10 Medicaid statutes, they would need a finding on that. If they
11 don't want one, that's fine, but that may have consequences on
12 other remedies available to the Relators.

13 MR. RUSS: Your Honor, I don't think it is just
14 Medicare. That was what I was trying to accomplish. It is
15 for any federal program. Right? So it's ADAP, Medicaid,
16 Medicare. The number of claims will be asked one time.

17 THE COURT: And how is that question proposed in that
18 first part of the verdict sheet?

19 MR. RUSS: What is the number of false claims, if
20 any, did Relators prove that Janssen caused to be submitted as
21 a result of any False Claims Acts violations you found in
22 Question 1, which would include any federal --

23 THE COURT: What was Question 1?

24 MR. RUSS: Did Relators prove by a preponderance of
25 the evidence that Janssen violated the federal False Claims

1 Act by unlawfully promoting Prezista or Intelence?

2 It's not tied to a payor.

3 THE COURT: All right. I mean, I'll -- like I said,
4 this may be addressed on the Rule 50 motion, but if Mr. Russ
5 wants to stand on that position, I'm not going to change this.
6 We have that verdict sheet.

7 My point was, let's make sure the written instructions
8 are consistent with that final verdict sheet, which means I
9 should put a period after the United States.

10 MR. RUSS: That's correct, Your Honor.

11 THE COURT: All right. Well, then, you're going to
12 revise that verdict sheet. We've had this discussion already.
13 I'm going to make just those two small minor revisions for
14 consistency purposes with what we've discussed, and there's no
15 other issues raised, based upon my reading of those final
16 instructions, and then we'll go from there.

17 Anything further then before we take this recess and
18 fix the technology and Relators need to get ready?

19 MR. RUSS: I don't think so, Your Honor. I've shared
20 a copy. If there's any typos or anything, obviously let me
21 know, but I don't think there's anything else from Relators.

22 MR. WYATT: So just for clarity, we read the copy as
23 conformed with the ruling the Court has made under the
24 position that the Relators have taken, so I don't have any
25 comments on that.

1 I do want -- I just want to be really, really crystal
2 clear as to what our position is going to be so no one is
3 surprised later.

4 We are going to oppose any effort to reverse engineer
5 how many state claims are bundled into the count of claims on
6 the verdict sheet later. So it's a point of law, it's a Rule
7 50 issue; we don't need to sort it out now. But I just -- no
8 one is going to say that they didn't have a heads-up about
9 this, and so I just want to be very, very clear --

10 THE COURT: I think you've been clear. They've
11 separated the liability question for each state, but they have
12 not separated, at least for purposes of the verdict sheet,
13 separated the -- identifying the number of claims or
14 allocating specific damages of each state. I don't think it
15 can be any more clear. It's obvious on the face of the
16 verdict sheet.

17 And I think, Mr. Wyatt, and I don't say this with any
18 -- I'm not being dismissive, but I think you've been very
19 clear on the record about what the concern is from Janssen.
20 So I don't see how the Relators can be confused by this. I'm
21 not confused by it, and I'm not even involved in this case.

22 You know what the objection is. And you're comfortable
23 with this verdict sheet going forward, knowing that the
24 Rule 50 motion will be drafted after if there's liability
25 found on these state claims.

1 MR. RUSS: Absolutely, Your Honor. The False Claims
2 Act can be used to recover that money. Those are claims to
3 the United States for the United States' money.

4 THE COURT: That's fine. And, again, folks, I'm not
5 litigating that issue today. I raised the concern there --
6 and we made some revisions to the verdict sheet, but that only
7 addresses part of Janssen's concern. I'm not saying you need
8 to concede and address all their concerns. I just want to
9 make sure the record is clear that that is the objection
10 that's still being noted about how these state claims are
11 being presented to the jury for purposes of the verdict form
12 and that that issue will be addressed, I'm sure, if there is
13 liability found on the state law claims at a later date when
14 you all get a chance to fully brief it to me.

15 But for now, this is what's going. Fair enough?

16 MR. RUSS: Yes, Your Honor.

17 MR. WYATT: Yes, Your Honor.

18 THE COURT: All right. So, folks, why don't you take
19 recess. Mr. Marketos, I know you need a little bit of time to
20 figure out, now that you have the verdict sheet and some
21 additional things, and we need time to figure out this
22 monitor.

23 So let me work on that during this break and I'm --
24 we've also -- just to give you a sense of timing, the jurors
25 will not be going to lunch until 1 o'clock. We extended it a

1 little bit because I do believe we should get at least one
2 closing done this morning, and they anticipate that.

3 So why don't we take that short recess, and then we'll
4 go from there.

5 MR. MARKETOS: Yes, Your Honor. It doesn't look like
6 we're going to -- if we take the recess, and then we're not
7 going to get the jurors to lunch at 1.

8 THE COURT: Why not?

9 MR. MARKETOS: Because it's three minutes until 11.

10 THE COURT: Yeah. You have 15 minutes. So it's
11 going to be a few minutes. You have no more than two hours,
12 right? So it can't be more than two hours.

13 MR. MARKETOS: Right. So it will be 1:15.

14 THE COURT: All right. So it's around 1 o'clock. I
15 get it. But why don't we stop wasting time here and go get
16 the closing put together so I don't have to make it 1:30.

17 MR. MARKETOS: I wanted to make sure that at
18 1 o'clock --

19 THE COURT: I'm not going to cut you off 15 minutes
20 before your closing.

21 MR. MARKETOS: Thank you, Your Honor.

22 THE COURT: You got it.

23 (A short recess occurred.)

24 THE DEPUTY COURT CLERK: Please remain seated.

25 (Brief pause.)

1 THE DEPUTY COURT CLERK: All rise.

2 (Jurors enter the courtroom.)

3 THE COURT: Folks, everybody have a seat. Members of
4 the jury, we've had a technical issue. We have lost this
5 monitor, and I will tell you I have no intention of delaying
6 anything. We're going to proceed with closings. I'm going to
7 ask you to -- you've got your movie screen down here, but with
8 only eight of you, you should be able to focus on this monitor
9 when things are being shown. If you need to adjust in the
10 back row, feel free. If you don't, you don't have to. I want
11 to make sure that you all can see that monitor.

12 Is that -- you want to shift over one?

13 Again, like I said, you have the monitor in front of
14 you. You have the one on the left. You all should be able to
15 view that. I want to make sure you know this is out, but the
16 show must go on. So we're going to move forward. I apologize
17 for that, folks, but I don't want to delay based on a
18 technical issue.

19 Can you all see that in the back?

20 THE JURY: Yes.

21 THE COURT: I'm comfortable moving forward.

22 I told you we were going to proceed with closing
23 arguments. We are going to hear from Relators' counsel this
24 morning, then break for about an hour lunch. We will hear
25 from Janssen in the afternoon and rebuttal argument from

1 Relators in the afternoon. We'll see how much time you may
2 have to even start talking about the case, but we'll address
3 that then.

4 So, Mr. Marketos, are you prepared with your closing
5 remarks?

6 MR. MARKETOS: We are, Your Honor.

7 THE COURT: With that, you may proceed when you're
8 ready.

9 MR. MARKETOS: Thank you, Your Honor.

10 Good morning. It is has been a long time since I got
11 to talk to you directly, a long time. It is now
12 June the 11th, and I think I last spoke to you -- to some of
13 you directly on May the 6th. Just a few questions I had to
14 ask from each you. And I know that you have been sitting
15 there paying unbelievable attention to what has taken place in
16 this courtroom for the last five weeks. Let me just say how
17 appreciative we are of the amount of time and attention you
18 have paid to this case. I want to thank you for your civil
19 duty, for your civil service, for the amount of time that
20 you've taken away from your families and your jobs and your
21 outside lives for us, for the system of justice, for the
22 Relators Christine Brancaccio and Jessica Penelow, for my
23 colleagues from Berger Montague, or my colleagues from my law
24 firm as well, Reese Marketos. And, frankly, for truth and
25 justice. It has been a long run.

1 12 years ago, 12 long years, Christine and Jessica have
2 been going after Janssen, and now it's time to finish the job.

3 Janssen's violation of the False Claims Act, off-label
4 marketing, and violations of the Anti-Kickback Statute.

5 Ladies and gentlemen, I'm going to walk you through the
6 evidence in this case, and I'm going to do it methodically,
7 the way that we did it during the case. It's important to us
8 because the evidence matters and the evidence favors the
9 Relators in this case, and so we're going to be methodical,
10 like we were with the witnesses and the documents, and please
11 just bear with me as we try to tell a story that took place
12 over nine years, and we try to show you with evidence and
13 testimony what actually happened. Because this is how the
14 veil gets lifted on a company that does not want to follow the
15 law, a company that favors profits over patients, over its own
16 employees.

17 Way back in 2006, Janssen's own guidance documents told
18 that you can't forecast, you can't build your strategies, you
19 cannot build sales targets that are based upon off-label
20 promotion of your drugs. And, listen, this is one of those
21 cases where companies, like specifically Janssen in this
22 case -- it's one of those cases where they'll come along and
23 they will say, Listen, we make some good drugs and they help
24 some people, and they've done very well for this segment of
25 the population. And that's, of course, what we're addressing

1 with these laws, because drugs that are good for some people
2 are bad for others if they're not used the right way. And at
3 the end of the day, you cannot decide, because you want to
4 make a profit, that you're going to skirt those laws. Not in
5 this country you can't. There's a reason that we have these
6 laws in place, and it's to make sure that companies stop and
7 think about what the end goal is. If you want to be in a
8 for-profit business, if you want to make and sell
9 pharmaceuticals and make billions of dollars, so be it. That
10 does a lot of good when it's done the right way. But when it
11 goes awry, when it goes amuck, when profits become the sole
12 focus, that is when our value system gets inverted and people
13 can become hurt.

14 But what did Janssen end up doing in this case? Well,
15 what they did was they started from the very beginning in 2006
16 and they built a sales model, a forecast, and a strategy that
17 they realized, they knew at the time, had off-label sales of
18 Prezista built in, and there was a reason for that. The
19 reason is because they had not ever, at any time, decided to
20 pursue a full label for that drug. They rushed it through an
21 early access system. They got it as quickly as they could,
22 and they wanted to get it on the market. And as result of
23 that, they had a narrow label for only treatment-experienced
24 patients. But that was not going to get the money. That
25 wasn't going to make Mr. Mattes's forecast. He had a profit

1 goal in mind, set from the start, and they were going to
2 attain those profits regardless, however they had to do it.
3 And so at the outset, as he told you, it would be wrong, I
4 asked him, it would be off-label promotion to include
5 off-label forecasting, correct?

6 Correct.

7 But when we walked him through the documents, when we
8 showed the strategies, when we showed the forecasts that,
9 themselves, that we were able to obtain from Janssen, showed
10 that they were incorporating off-label sales in order to make
11 their sales goals from the very get-go, he said, Yes, because
12 he had nowhere to go.

13 And that's how it got started. See, we did not wait to
14 bring you the president of the company. The first two
15 witnesses we called from Janssen were Mike Iacobellis, the
16 national sales director, and Glenn Mattes, the former
17 president. We wanted you to know from the very beginning that
18 this was a top-down plan. And so we called them to the stand,
19 and we put the documents in front of them, and they testified,
20 and we found out what happened. And then they left the
21 courtroom.

22 Right off the bat, from the very get-go, what you
23 cannot do, you cannot set sales compensation targets for your
24 sales staff that incorporates sales of off-label drugs. What
25 do you think is going to happen? That's in their own guidance

1 documents. But from the get-go, from the beginning, and all
2 the way through, the sales targets for the sales
3 representatives, the incentive compensation plan was
4 incorporating off-label sales, and they were rewarded for it.

5 But here's the part that I want you to make sure we're
6 focusing on. There's so many discussions throughout this case
7 about dollars, about money, about influence, about payments,
8 cash. But what starts the process? From the very beginning,
9 patients were telling pharmaceutical companies, living with
10 HIV, both naive and more experienced, HIV patients are
11 concerned about the side effects of HIV drugs. Why? We've
12 heard about this. Because now that the drugs, thank God, the
13 medications had advanced. Everyone's living a lot longer, and
14 thankfully, thankfully, there is science to thank for that.
15 But what happens now? Now you have to worry about the side
16 effects of the drugs that you're taking. How they impact
17 cholesterol, triglyceride levels. I did my homework, this
18 patient said. I wanted to get my lipids down, and I found out
19 about Reyataz before my doctor did.

20 These patients are worried about their hearts because
21 they've been on these drugs for a long time, and we know what
22 they can do.

23 Johnson & Johnson's credo, the parent corporation, is
24 to protect the patient, the customer, the employees, and
25 business partners. But this particular subsidiary, this

1 particular company, they inverted the paradigm. They ended up
2 going straight to the bottom line, straight to profits, and
3 they skipped over their patients and they skipped over the
4 employees.

5 Now, we know that the federal anti-kickback laws are in
6 place to make sure that pharmaceutical companies like
7 Tibotec-Janssen, specific to Tibotec-Janssen, and other
8 pharmaceutical companies aren't able to spread their money
9 around in a way that influences doctors. The whole concept is
10 we don't want to have to go into the doctor, none of us do,
11 and wonder if that doctor is making a decision because of some
12 amount of money that he or she was paid by a pharmaceutical
13 company with a for-profit interest. It's not a difficult
14 concept. But at the end of the day, Janssen, at every step,
15 no matter what their compliance documents say, no matter what
16 they knew about paying remuneration, including anything of
17 value, this is exactly what they did. They took the
18 compliance documents, they took the warnings about what not to
19 do, and they used it as a playbook. And we'll see why they
20 did that.

21 Now, state and federal false claims laws, they knew
22 also prohibit off-label marketing, so you got two types of
23 conduct in this case that we're really worried about with
24 these laws: when pharmaceutical companies decide that they're
25 going to go off-label for things that their drugs are not

1 proven safe for, and then payments of money or anything of
2 value to the decision-makers that the patients should not be
3 worrying about their decision-making process being corrupted.
4 Doctors. And they knew that these laws had been enforced over
5 and over again. It doesn't matter if it's a cancer drug or an
6 HIV drug or in some cases an antipsychotic or anticonvulsive.
7 It doesn't matter if you are getting a protected class of
8 drug. In this country, if you get the privilege of FDA
9 approval, if you want to play by the rules of the game, you
10 must follow them all. You don't get to say, I'm going to make
11 a big profit and get FDA approval to sell our drugs in this
12 country and only pay attention to the parts that you like.

13 They knew from the get-go that they could be caught and
14 they would have to pay the money back if they were caught.
15 Over and over again, the warnings came from Johnson & Johnson,
16 but Janssen decided to ignore them.

17 Now, at the end of the day, the people tell the story.
18 And so what did we do in this case? Well, it's not one of
19 those cases where you have a whistleblower who steps forward,
20 and then the company defends themselves by bringing 20 members
21 of the sales force and saying this didn't happen, or
22 upper-level management and documents and say this didn't
23 happen. No. This was a case where seven former sales
24 representatives, district managers, regional managers, came
25 forward to tell you under oath what was really going on at

1 this company. And Janssen's method of disputing that
2 testimony was to attack the people that were testifying, go
3 after their credibility. The people who were at the top of
4 their organization on the sales force all of a sudden were
5 liars for telling the story about what took place over time,
6 methodically with names and dates and receipts, over and over
7 and over again. I'm going to tell you that story as fast as I
8 can because I got to summarize a five-week trial in the next
9 hour and 45 minutes. So bear with me and buckle up.

10 Speaker selection. What was going on in March of 2006?
11 The drug Prezista was about to launch. And so what did
12 Janssen do? Well, of course, they wanted to sell their drug.
13 Of course, they wanted to make sales forecasts. So they did
14 two things at the same time: They got their sales force ready
15 to promote the drug, and they went right to a speaker bureau,
16 a promotional speaker bureau.

17 Ladies and gentlemen, I think the evidence has shown
18 during the course of this case that that type of program in
19 itself is about the most -- it's about the most corrosive type
20 of program you can possibly have, because it has all the
21 auspices, all the outward appearances of doctors speaking to
22 doctors, but, fundamentally, it is a way for the
23 pharmaceutical companies to funnel cash to health care
24 providers, to get them loyal to the brand, to get them
25 prescribing the drug and, in this case, also to get them

1 prescribing off-label.

2 So when you hear from Janssen that this is about an
3 educational program, you know, we call things what they are in
4 life, right? Dog, cat, promotional speaker bureau. It's not
5 an educational program. That wasn't what it was for.

6 You may have had a tangential benefit. You may have
7 had an additional benefit of having some educational value
8 associated with speaker programs. But they put 150 doctors
9 together from the very get-go three months before this product
10 even launched, Prezista. And they did that by identifying
11 doctors who wrote the most prescriptions for HIV drugs.

12 And so they put them in buckets. The highest
13 prescribers being A, the mid-volume being B, and then C was
14 thought leaders associated with academia. And they went after
15 A, speaker development names. They went after the A lists.
16 Some of these doctors you heard from in this trial.

17 I mean, Mr. Wilhelm told you what they were doing. He
18 flew here, took the witness stand, was on for over a day. He
19 told you exactly what Janssen was doing. Top ten AIDS by
20 state and rank. Top Aptivus. They would go ahead and see who
21 were the top prescribers for competitive drugs, other drugs
22 that were already out there on the market, protease
23 inhibitors, and they would identify the doctors that were most
24 likely to reap a profit for Janssen.

25 They got their 150 speakers before the drug even

1 launched.

2 And finally, when Prezista's label came out in June of
3 2006, they were ready to go. They were going to send the
4 sales force out with messages, and they were going to get the
5 speaker program burning with cash.

6 And we know from an internal strategy, we got their
7 internal strategy documents, that the forecasts themselves
8 were aggressive and they weren't tied into the label. The key
9 forecast assumptions right off the bat were that there was
10 going to be parity with Reyataz on lipids. Well, turns out
11 that wasn't true.

12 Their commercial strategy was going to be to
13 aggressively promote Prezista's value proposition. And they
14 already planned to ramp up prescriptions. And then it was
15 time for the pressure cooker.

16 In July of 2006, what happened? The drug launched.
17 Three weeks into it, they're not making sales. Why is that?
18 There's pushback on the lipid profile. There's pushback on
19 whether this drug is effective or not.

20 And so what happened? What was the culture like at
21 Janssen? Ms. Sara Strand came and told you about it for a day
22 and half herself. "It was not pleasant. At the beginning, we
23 were so far behind goal, the president would yell at us on
24 conference calls. He would yell at us at a national sales
25 meeting, you know. It was a very high-stress environment.

1 Just not good."

2 Now remember who these people are. Ms. Sara Strand,
3 Mr. Mark Wilhelm. Not only are they high up in the
4 organization, they're highly trained sales representatives who
5 are experts in HIV drugs. They were being barked at and
6 yelled at by top management for a strategy that top management
7 had itself concocted. That was the problem.

8 Mr. Glen Mattes, he wanted to create positive anxiety
9 and have each and every one of his managers focused. So he
10 called a meeting, and you heard everybody testify about this
11 meeting, the brainstorming session, about how they were going
12 to get this product to sell. And that's when the off-label
13 took off.

14 Positive anxiety. I asked him What was that?
15 Certainly wanted them to understand that that performance was
16 not consistent with expectations.

17 So the guy who said the buck stops here, he passed the
18 buck. Instead of blaming himself for missed forecasts,
19 instead of blaming their strategy for getting a narrow label
20 for the drug and rushing it to market, instead of going back
21 to the one member of the board that he reported to and saying,
22 I messed up, he took it out on the sales force and the people
23 who reported to him.

24 You know, I asked Mr. Iacobellis, Was he using those
25 words loudly? He said, Yeah. So loud disappointment? I'm

1 not even sure what that is, but of course he was yelling.

2 Loud disappointment.

3 It only got worse from there, Sara Strand said. They
4 had the meeting, and that's when the wheels really started to
5 run. How can we change our messaging? That's when we really
6 started to realize we could try naive patient, and we could
7 also talk about it's lipid friendly. Because that's the main
8 reason that Reyataz was getting so much business, was because
9 of the lipid profile being so friendly.

10 So they're going to go in two packs. They're going to
11 promote the drug for patients who it's not approved for,
12 naive, and they're going to minimize the side effects by
13 calling the drug lipid friendly for HIV patients.

14 So at that first meeting, I mean, Sara told us they had
15 to go and get a drink afterwards because Glen had ripped them
16 a new one.

17 And then what happens? The MIR machine kicks up. And
18 boy, you must be the most expert group of people on medical
19 information requests in history. There was a lot of
20 discussion about it. But it was microcosm of what was going
21 on in this case. Here, you have laws in place that prohibit a
22 sales representative from talking to a doctor about off-label
23 uses of a drug. Why? Because it's not approved, and you're a
24 promotional representative, promoting the drug for your
25 company. You can't have that discussion with a doctor because

1 you don't want the doctor to have his or her medical
2 decision-making corrupted. So you don't do it. And if the
3 doctor has a question, you have to have them send that form in
4 and get the information themselves. It cannot be solicited.
5 You cannot interfere with the process.

6 That's not what happened here. Right off the bat, MIR
7 forms are being widely used to get the 48-week data into the
8 hands of all customers. I know that Janssen is going to try
9 to explain this one. But this is what was happening. This is
10 what was actually happening. You heard it from all the
11 witnesses who worked for them. They were being told that
12 their sales performance as a metric was going to depend on the
13 number of off-label MIR requests that doctors solicited
14 themselves.

15 Selecting speakers. Well, top 25 physicians by
16 dollars. That's how they picked them. They didn't pick them
17 based upon how many papers they had written. They did not
18 pick them based upon any other criteria. Don't let them fool
19 you. They focused on the money. Top 20 Prezista writers in
20 the nation. They would rank them, and they would track their
21 prescriptions. Period. End of story.

22 What else did they do? It's time to get the off-label
23 studies going. You've got the MIR requests. You've got the
24 sales force delivering messages about lipid friendly, lipid
25 neutral, minimal impact on lipids, go, go, go, go, spread the

1 message. But now we're going to use off-label studies, and
2 we're going to collect them, we're going to talk about how to
3 use them in sales meetings internally, we're going to talk
4 about how to use them competitively with doctors.

5 And you heard from the witnesses who actually care
6 about what happened. They would tell you how they used them.
7 Off-label studies like this junk study that Mr. McSherry
8 acknowledged, himself -- and we'll talk about him later -- was
9 a real problem. This was a fake study. It had 48 healthy
10 patients. It was called the DART study, and it was circulated
11 among the sales force far and wide in New York, out to
12 California, back and forth, to use with doctors to try to show
13 that Prezista and Reyataz had the same level of lipid profile,
14 which we all know what was not true.

15 Mr. Mattes set the culture from the top, reminding
16 everybody of the expectation he has for all of them.
17 Constantly putting pressure to make forecast.

18 Now, the percentage of physicians writing Prezista from
19 2006 to 2007, they had a \$22 million number for the second
20 half of 2006, and a \$132 million target for 2007.

21 And I walked through all of this with Mr. Mattes, if
22 you recall, showing him that year after year they were ramping
23 up sales even though they knew that off-label sales were
24 incorporated into the forecast. Spontaneous, of course.

25 Right off the bat, you knew that they had a natural

1 playfield. That is careful communication for, This is all we
2 are permitted to sell to.

3 Segment H. That's the highly treatment-experienced
4 patients who have failed two or more. Okay. More than one.
5 Two or more. Resistances. But right off the bat, they had to
6 play in earlier, earlier disease phases, all the way down
7 until eventually they were going to proceed into the
8 treatment-naive. And they incorporated those forecasts and
9 targeted those patients long before they ever had a label for
10 treatment-naive.

11 Please start the calculation metrics at \$95 million,
12 Mr. Mattes said. Let's go set up some time to talk. Touch
13 base with Brad and keep the circle of communication small at
14 this point.

15 He had pressure to hit targets in 2007 because he'd
16 whiffed so bad in 2006.

17 Now, you know, there was a doctor just -- you heard
18 from -- I can't remember what day. I've lost track of time.
19 I think it was yesterday we heard from Dr. Tony Mills. And
20 just one thing he said offhand was he was at a breakfast
21 meeting having -- with somebody from Janssen at a major HIV
22 meeting, and they were discussing research and they mentioned
23 they were considering doing a trial looking at using Prezista
24 in treatment-naive patients. "And I got angry because
25 Prezista wasn't for treatment-naive patients."

1 Well, of course not. And see, Dr. Mills, he didn't
2 remember people talking to him off-label because that's how
3 insidious it is. But that's what that was.

4 Now, Ms. Candice Long came along, and she started
5 focusing on Intelence. That was approved in January of 2008.
6 Ms. Candice Long came over from the Risperdal side of the
7 equation. Right? Mr. Glen Mattes, he was on the Topamax drug
8 before he came over to start this company. And we'll talk
9 about that later.

10 "The story of the oversight for QD once daily does
11 poorly reflect on the ability of the organization to make
12 accurate and timely decisions." This is her colleague telling
13 her at launch, "Careful. The Prezista launch forecast is
14 still in their heads." He's talking about the sales force.
15 "They're still worried about our company's strategy."

16 And now, what happened? They didn't get a once-daily
17 dose approval for Intelence. And that's going to make it hard
18 to sell because, as everyone knows, taking a drug once a day
19 is a lot easier than taking it twice. And when you have to
20 take it twice a day, it makes the drug harder to sell.

21 Back to speaker selection. Let's rank the speakers
22 based on the number of prescriptions. That's it. Number
23 after name is total Prezista scripts to date as of May. That
24 was Kim Saladana. Ranking the speakers by their
25 prescriptions.

1 Let's go ahead and pick them, number 1 being the
2 highest priority. Number of scripts for Prezista. That
3 speaker selection, do you see anything in there, by the way,
4 do you see anything in there about number 1 being the highest
5 priority, education, experience? No. It's how many scripts
6 are they writing.

7 And then if a speaker who they had paid to speak on the
8 program stopped writing enough of the drug, they would kick
9 them off. That's how you know what the game is about. It's
10 all about payments of money in exchange for prescriptions.
11 Inducing and rewarding.

12 And they also knew they weren't supposed to talk about
13 it. "I would recommend we stay away from the discussion
14 around prescribing levels." Do you remember that one? They
15 knew that this was -- they knew what this was. They knew what
16 it was. A doctor who has plenty of experience writing the
17 drug has spoken on a speaker bureau and now you kick him off
18 because he or she is not writing enough prescriptions. What
19 is that?

20 "Writing prescriptions for Prezista was a measure of
21 whether or not a speaker would stay on the program and keep
22 getting paid. True, Mr. Mattes?

23 "It was probably one of the criteria." No kidding.

24 We asked Sara Strand, "What about speakers whose volume
25 fell off while they were being paid? What happened to them?

1 "So we had to kick some of them off. If they weren't
2 writing enough, then we would go and tell them we're not going
3 to renew your contract; you won't be a speaker next year."

4 That tells you what the game was all about.

5 Under the law, if one purpose, just one purpose of the
6 speaker payments was to induce or reward doctors for
7 prescribing Prezista and Intelence, that's a kickback. That's
8 what you can't do. And that's exactly what they were doing.

9 Then they would track them. In each region, New
10 England speaker sales performance, track the speakers by
11 prescription for Prezista and Intelence. Sometimes they
12 weren't so careful with their communication, and we found
13 them.

14 Midwest speaker sales performance. They're tracking
15 them by their performance. And look how they've segmented
16 them. They have actually categorized the doctors into
17 different segments of behavior: Pioneers, conservatives,
18 protectors. They were tracking the doctors' actual
19 prescribing habits and categorizing them and tracking their
20 prescriptions.

21 And, of course, the witnesses who we called to testify,
22 Sara Strand, Mark Wilhelm, Matt Grooms, Joe Holshoe, Chrissy
23 and Jessica themselves, of course they told you this was what
24 was going on. "We're not tracking speaker sales," they told
25 you, except I had 400, 400 documents in evidence from their

1 experts who they paid in real time, partners in loyalty
2 marketing.

3 Excel spreadsheet with the data, tracking every
4 permutation of sales force, plus speaker, plus MedForce, plus
5 Intelence. That's what that was all about.

6 Yes, they were tracking speaker prescriptions.
7 Absolutely. And it's in evidence. That's Plaintiffs' Trial
8 Exhibit 602.

9 The purpose was to drive sales. Sara told you. She's
10 the regional manager, and she's telling you what they were
11 doing, under oath. "We were trying to drive the sales of the
12 speaker themselves." And that's why they were paying the
13 money.

14 Mark Wilhelm told you the same thing. Now, if you
15 think about it, that's Sara and Mark. They are over,
16 together, the entire sales force across the entire
17 United States. That's the Eastern and the Western regional
18 managers. They both come into court, neither one of them is a
19 Relator, and they told you what happened. The purpose was to
20 drive sales. No kidding.

21 Dr. Aaron Glatt. He doesn't take pharmaceutical money.
22 He is the only designated expert in this case who is going to
23 testify -- who did testify -- about what is reasonable and
24 necessary for prescriptions, and he's the only expert
25 permitted to testify to you about the lipid profiles, about

1 whether or not this drug could be harmful to patients.

2 He is an infectious disease expert. He is the chief at
3 Mount Sinai. He has been an HIV and infectious disease expert
4 for years, and he looked at the lectures that they were giving
5 on these speaker programs, and it's all the same thing. It
6 was repetitive, over and over again. He said there was no
7 educational value.

8 Nearly nine -- 9,000 speeches, right? 150 speakers
9 initially; then they went up to 335. The same slide decks,
10 multiple repeat attendees over and over again.

11 Where did they go? Where do you think? We didn't just
12 pick some -- we didn't just cherry-pick. Yes, there were some
13 that were held at hospitals during the day or in a doctor's
14 offices during the day. And then where were they at night?
15 Where were they during the weekends? They were at some of the
16 nicest places in the country. Wining and dining, not just the
17 speakers, but everyone else in attendance.

18 Now, I could let it run. This exhibit is in evidence.
19 You can see the types of places that they were taking these
20 doctors to. When we had Janssen's witness on the stand,
21 Ms. Kaucher from compliance, she couldn't tell you what a
22 modest place was. Do you remember that? They were supposed
23 to be modest and educational, and that is anything but. These
24 were some of the finest places that they could take doctors
25 to.

1 It goes on. You get the message. What was the plan?
2 That's what this promotional speaker bureau was. Take them to
3 fancy restaurants; pay the speakers a lot of money to give the
4 same speech over and over again.

5 I'm going to wait for it to end. There was a
6 five-prescription requirement. Remember that? Just to get on
7 the speaker bureau. And, look, this is -- this is not
8 something that Janssen is arguing with, believe it or not.
9 \$17 million put into the hands of doctors, just the speakers.
10 That doesn't account for the millions and millions of dollars,
11 tens of millions of dollars that they spent on these fancy
12 venues for the other attendees over the course of 2006 and
13 beyond.

14 Doctors traveling to Hawaii for four days, getting paid
15 \$5,000 for two 45-minute-to-an-hour speeches, staying at
16 hotels. Over and over and over again, what were they
17 measuring? Physicians by dollars. Now, this is Janssen's own
18 documents, their own experts who Janssen pays money to to
19 determine how effective their influence actually is on
20 doctors' prescribing habits, in real time. Not in litigation.
21 Not in a lawsuit. In real time.

22 Now, pharmaceutical companies, they know how to market,
23 don't they? They spend billions on it. They know what works,
24 and they track their performance to the nth degree. It's not
25 a surprise. Speaker programs are an effective way to make a

1 lasting impact on prescribing behavior. Of course it is.

2 That's why they do them.

3 Now, Intelence is an FDA label, two taken twice daily.

4 Never changed. Not once to the end of time, from the start to

5 the finish. That's a problem. That's an impediment.

6 Dr. Mills said, "It wasn't like something that would have ever

7 crossed my mind to use once a day or to use in a naive

8 patient."

9 Well, it crossed Janssen's mind because that's how they

10 could increase their sale. That label was so narrow. It was

11 a twice-daily drug for highly treatment-experienced patients.

12 How were they going to get their sales forecasts? Well, they

13 ramped up the targets, and the sales force was comped no

14 matter whether the sale was on-label or an off-label

15 prescription.

16 And it worked. Year after year after year, they sold

17 more and more of Prezista and Intelence, until they were over

18 \$338 million in 2010.

19 \$133 million for Intelence just in 2010. Over time,

20 that went up. It got to the point where their naive share,

21 Intelence naive share, was being targeted. That's a drug

22 that's not for naive patients. But they targeted it. They

23 went after the A through D segments from 2008 through 2009,

24 spontaneous, of course.

25 Now, they calculated mathematically the value of a

1 Prezista patient. The lifetime value was \$32,000 per
2 prescription. Because once a patient gets on that drug,
3 they're on it for awhile. They're on it for awhile. And they
4 know how much every prescription is worth. It's not the
5 90-day bottle. They're on the regimen. They are not going to
6 switch off of it, and they know that.

7 What's going on in the marketplace? Lipid friendly,
8 low impact on lipids, low impact on cholesterol. Low lipid
9 profile like Reyataz, minimal impact on lipids. Over and over
10 and over again. 620,000 times we have records of their sales
11 force contacting doctors, and they were delivering the same
12 messages over and over and over again. That's what all of the
13 witnesses called by the Relators said and Janssen's own
14 witnesses eventually -- or eventually.

15 Low impact on lipids. Is that true? This was their
16 message. And we're going to come to find out what actually
17 took place back with the FDA.

18 The only written document with the FDA's response to a
19 Prezista lipid message was a -- one that I got Mr. Patel to
20 tell us all about. One. One document. The claim that
21 Prezista had a lower impact on cholesterol was misleading
22 because it minimizes the risks associated with the use of
23 Prezista. Specifically the FDA said it suggested that
24 patients will not experience an increase in cholesterol,
25 low-density lipoprotein and triglycerides, when this is not

1 the case. It's false.

2 And they pointed out that the drug itself on its own
3 label shows hypercholesterolemia, hypertriglyceridemia, and
4 low-density lipoprotein increases. This is not small stuff.
5 This is not a minor side effect. This is not something that
6 you can take lightly, but what is it the -- what did the FDA
7 say and then what did Janssen do?

8 The DDMAC told them this applies to this claim as well
9 as future promotional materials containing the same or similar
10 claims or presentations. And we remind you, sir, that only
11 written communications from the government are considered
12 official.

13 Serious adverse drug reactions for Prezista. Dr. Glatt
14 called it a triple whammy, and, I mean, out of all the doctors
15 that you saw in the case, he was the only expert designated or
16 permitted by the Court to testify on the standard of care.
17 The only one. Janssen didn't bring one. They have all the
18 access to doctors in the world, a lot of doctors on their
19 payroll, and they did not have a single doctor testify from
20 the stand as an expert witness about the lipid profile. They
21 didn't put anyone up there to contradict Dr. Glatt.

22 So it's a real triple whammy. They're at risk for the
23 disease from HIV itself. They're at risk from the medication,
24 some of them that were used to treat HIV, and then, even if
25 they get it, they're at risk for not responding as well to

1 some of these lipid-lowering agents.

2 So they can't just take Crestor. They can't just take
3 a drug to help lower the lipids because it is contraindicated
4 for that. It is a real problem.

5 He said there are significant cardiovascular
6 complications. Blood vessels get clogged. Heart disease can
7 lead to stroke, kidney dysfunction, peripheral vascular
8 disease, troubles with your blood vessels to your legs. It
9 can impact your entire body. Dr. Glatt told us that. He's an
10 expert, and he doesn't take pharmaceutical money.

11 Now, what else did he tell us? There's a paper
12 published at one of the retrovirus conferences that
13 specifically shows that outcome of cardiovascular events, no
14 longer lipid problems, but the cardiac injuries were higher in
15 the Prezista group than in the Reyataz group. Specific
16 evidence of it.

17 And that's what was going to happen if you minimize the
18 side effect of this drug.

19 He testified about the appropriate standard of care for
20 HIV patients between 2006 and 2014 for the lipid claims. For
21 the lipid claims, it would be inappropriate for the entire
22 period of time. The lipid claims are lipid friendly, lipid
23 neutral, minimal impact on lipids, all of the messages that
24 Janssen was having its sales force deliver to the marketplace
25 and to doctors. Was there a consensus? We asked the only

1 expert in this case in the medical community, during this time
2 period, even though Prezista was preferred, if that the lipid
3 side effects of that drug still had to be factored into a
4 prescribing decision. Absolutely. We want to make sure
5 they're alive, not only from their HIV, but they don't get
6 heart disease and stroke. Cardiac injuries were higher in
7 Prezista than in Reyataz.

8 In that same group of patients, lipid-impacted HIV
9 patients, prescribing those patients Prezista violated the
10 standard of care for HIV patients. That's those patients who
11 had a lipid diagnosis or a lipid issue. Prescribing them
12 Prezista instead of Reyataz violated the standard of care.

13 Did Reyataz, during this time period, contain the same
14 warnings on the label? No, it did not. Now, we talked about
15 the idea that the guidelines put Reyataz and Prezista on a
16 preferred status. But in the majority of cases, Dr. Glatt was
17 asked, anyone who has a lipid issue should be prescribed
18 Prezista? Do you recall that testimony?

19 He said specifically -- can you assess a percentage of
20 anybody who you might switch from Reyataz to Prezista if they
21 had a lipid issue because they were worried about jaundice?
22 5 percent. 5 percent. That's it, because the lipid issues
23 were such a big problem.

24 Now, do you remember this from opening statement? The
25 FDA reviewed Janssen's promotional materials, and all

1 promotional materials were approved by the FDA? That's not
2 our slide. That was Janssen's from opening statement.

3 Here's what you were told. Every single piece that was
4 used with a physician you're going to hear went to the FDA
5 approval -- for approval. All of those materials were
6 approved by the FDA. That's what you were told in the opening
7 statement by Janssen. We have a whole department. They don't
8 get used until we hear back from the FDA. There are a number
9 of approved messages that dealt with it. Nobody disputes,
10 they said, blessed by the FDA as having a low impact on
11 lipids. Nobody disputes approved by the FDA. Minimal impact
12 on lipids. Nobody disputes proven impact on lipids. It's
13 okay. It's okay. It's okay to say. That's what they told
14 you at the outset of the case. What actually happened? I got
15 Mr. Patel on the stand. Low impact on lipids. Never received
16 a written advisory opinion from the FDA.

17 "Do you remember that testimony for the use of the
18 message 'low impact on lipids'.

19 "Correct.

20 "Minimal impact on lipids?

21 "True.

22 "Never received a written advisory opinion approving of
23 the message 'proven lipid profile' for Prezista?

24 "True.

25 "Never received written approval for the message 'lipid

1 friendly' for Prezista?

2 "True.

3 "None of those messages were approved. The only
4 official communications from DDMAC are those in writing?

5 "Correct.

6 "The FDA may provide comment but only those in writing
7 are considered official?

8 "Correct."

9 That's what he told us. Since 1985, it does not matter
10 if you are advertising or promoting to patients, to consumers,
11 to doctors, every message you deliver must be true and may not
12 minimize side effects, regardless of its intended use.

13 But what did he do? After that letter, April 2009,
14 from the federal government, Janssen continued to put the
15 message out. "Proven lipid profile to doctors. Correct?

16 "Yes. We did continue.

17 "After this letter was received, you continued to say
18 low impact on lipids?

19 "Yes, that's correct."

20 That's what he told us.

21 And now you're being instructed on the law by the
22 Court. You've heard testimony from a Janssen employee,
23 Dr. Patel, about the FDA silence in response. And what we
24 learned from him is that they decided if they sent in
25 materials and never heard back, that somehow that was FDA

1 approval for their messages, even though the one letter they
2 got back said this is false and misleading. Right?

3 You heard him testify that Janssen considered the FDA
4 silence in response to those submissions as the FDA's indirect
5 or tacit approval of Janssen's advertising. You're instructed
6 there is no statute or regulation that says the FDA's silence
7 means it has approved of a promotional advertising submission.
8 Of course not, because as he told you, only the opposite is
9 true.

10 But the sales representatives would tell doctors
11 Prezista was lipid friendly. Yes. How do we know that?
12 Thankfully, Ms. Brancaccio had a recording of Nancy Bartnett.
13 Right, you had the recording. You heard it.

14 And then I finally asked her, "If the truth is that
15 Prezista was not lipid friendly, if calling Prezista lipid
16 friendly is off-label promotion because it minimizes side
17 effects, then you were engaged in off-label promotion for a
18 very long time?

19 "So, yes."

20 We can't do better. We can't do better in proving a
21 scheme to promote a drug off-label than to have the people who
22 were doing it testify under oath to you, the members of the
23 jury, that that is what was happening. We can't do better
24 than that.

25 Here's the issue, though, and this is the part that is

1 the most disturbing. The strategy was to eliminate the
2 perception of Reyataz as most lipid friendly, to drive
3 awareness of low impact on lipids. This is that message that
4 is false. To drive awareness of the low impact on lipids
5 claim over 96 weeks. They're going to push, push, push, push
6 to get past Reyataz.

7 They knew 30 percent of patients switching for
8 tolerability reasons have hyperlipidemia. 30 percent of
9 patients have a lipid problem, significantly elevated lipids,
10 and they're going to go and do what? Tell doctors not to give
11 it to those patients? No. Eliminate the perception of our
12 competitor as the most lipid friendly and drive awareness of
13 low impact on lipids over 96 weeks.

14 I didn't write this document. Janssen did.

15 And they knew. They knew that the government would
16 take this seriously. They knew, and they risked it anyway.

17 How? Because the plan for Mr. Mattes from the
18 beginning was to put the same mechanisms in place that he had
19 put in place with a drug called Topamax right before he
20 started this company, Tibotec. Right? He knew, and he
21 planned to put the same marketing and the same speaker bureau
22 programs in place.

23 And then in 2010, the corporate integrity agreement,
24 the Department of Justice brought the hammer on Topamax for
25 off-label marketing and payment of kickbacks to doctors.

1 They knew it was material to the government. They knew
2 they'd have to return the money if they got caught. But they
3 did it anyway.

4 Look what they did with their sales. P/I gross sales
5 expected to reach \$2.6 billion. Prezista growth sales, almost
6 a billion dollars in one year in 2012. They were good at
7 selling it.

8 And, ladies and gentlemen, let me make sure that I'm
9 clear about this, because the response from Janssen, of
10 course, is going to be but this drug helped patients. It
11 helped some patients. It helped some. And nobody from the
12 Relators will ever say otherwise. Chrissy and Jessica won't
13 say that. What were they having a problem with? Pushing the
14 drug, minimizing the side effects, selling it for use with
15 patients who it would not be good for.

16 And Intelence, all the way up to 233 million. In 2010,
17 they're about to hit over a billion dollars combined. One
18 year. One billion gross demand in sales projected for 2011.

19 They even show you the payor mix and what percentage
20 was paid by Medicaid. 16 percent. Knowing that that patient
21 population, Medicaid was paying for a large portion of their
22 drugs, they tracked the government payors of their drugs.

23 And for Intelence, they did the same thing. Medicaid,
24 15 percent.

25 Now, what happened? Boy, this is an interesting story.

1 It's September of 2010, and Ms. Joanne Cesario, a sales
2 representatives in a different district, from New Jersey,
3 takes to compliance health care violations, health care
4 compliance violations. What did she say? Well, let me just
5 tell you, we only found out about this in the middle of this
6 trial, because for years Chrissy and Jessica knew that this
7 had taken place. They knew that another sales representative
8 had reported off-label marketing concerns to Janssen, to their
9 compliance department. And so in this lawsuit, they socked
10 the documents.

11 Show us what happened to Joanne Cesario. Show us what
12 happened to the investigation. Nothing for years. For years
13 they hid it. We'll come back to that in a moment because that
14 has an interesting ending.

15 They knew, Janssen knew -- this is Dr. Amit Patel's own
16 compliance document -- that it's on-label if you make claims
17 regarding the product indication, it's efficacy, dosing, and
18 administration consistent with the FDA-approved package
19 insert, the label. But it is false or misleading to make
20 product claims not consistent with the FDA-approved package
21 insert, the label, or not supported by substantial evidence or
22 substantial clinical experience. That's not up for debate.
23 They knew it.

24 If you do any of the following, if you promote a drug
25 for a different use or indication, for a different dose, for a

1 different patient population, a different dosing schedule, a
2 different stage of the disease, that is off-label, and they
3 knew it, and they were doing it anyway.

4 How about this one? Where -- what are the off-label
5 opportunities for the NNRTIs Intelence? Where is Intelence
6 getting the business today in the earlier segments? Sometimes
7 the careful communication slipped through the cracks.

8 And who came into court -- who came into court to
9 answer for this one? He was talking about promotional
10 opportunities off-label for Intelence because they needed to
11 sell more drugs. Nobody ever explained it to you.

12 Now, what did we learn about Joanne Cesario? At a
13 district meeting in June, she specifically told Janssen, among
14 other things, that her superiors were distributing these
15 off-label studies and using them, using them with the sales
16 force. Okay? That's what they were doing. Off-label
17 studies, using them with the sales force to help compete with
18 other drugs.

19 Allegation is substantiated.

20 What happened to Mr. Murphy? What happened to Ms.
21 Peterson? This one was really interesting. This shows you
22 what happens when Janssen wants to cover something up.

23 Ms. Cesario said, "Look, we're getting compensated on
24 sales of Intelence. And at the end of the day, our
25 compensation model is not fair because we had a narrow label,

1 our opponent has a full label, and we're being penalized
2 unless we sell off-label."

3 What do they say? Hey, sorry. Your complaints are
4 irrelevant. Your complaints are irrelevant, Ms. Cesario.

5 What happened to Joanne Cesario after she made these
6 complaints? Well, Janssen withheld the documents from us in
7 litigation. Jessica Penelow told you that she got fired for
8 reporting it, and she did.

9 And then they took the stand, and they told you nothing
10 was ever substantiated. And we had to pause Ms. Kaucher's
11 testimony and get our hands on the documents, finally. And
12 that was all false.

13 "Maybe as much as 70 percent of Intelence use is
14 off-label."

15 Well, no kidding. Because that's how they were pushing
16 it.

17 The DeJesus study, July of 2010, funded by Janssen, 23
18 patients, over and over and over again using that study with
19 doctors.

20 Now, they had lots of pretty compliance documents
21 telling them what they could and could not do. They knew that
22 the government did not want to cover the cost of prescription
23 drugs when they violate the Anti-Kickback Statute or the False
24 Claims Act.

25 "We want to ensure that our business is conducted in an

1 ethical manner and within the law of the Johnson & Johnson
2 credo."

3 See, that is Johnson & Johnson. That is Johnson
4 & Johnson. But that was not Janssen. That was not this
5 entity.

6 They knew that the government does not want to cover
7 the cost of prescription products when they violate the
8 Anti-Kickback Statute, exchange anything of value in return
9 for business. False Claims Act, selling off-label,
10 misrepresenting a product, that's this case. And they knew it
11 was wrong.

12 They give examples of their own products' reimbursement
13 rates, Topamax, Risperdal. Both of them, both of them ended
14 up being the subject of a corporate integrity agreement, a DOJ
15 enforcement. Both of them were in protected drug classes,
16 both of them promoted by Mr. Glen Mattes's crew and
17 Ms. Candice Long's crew. They knew about it. They knew this
18 was wrong, and they did it anyway.

19 Ms. Virginia Evans, who specializes -- an expert
20 witness in the subject matter, specifically told you that the
21 government does not want to cover the cost of prescription
22 products when they violate the following. She said it would
23 go further than that and say the government does not cover the
24 cost of prescription products when they have been provided in
25 violation of the Anti-Kickback Statute or the False Claims

1 Act. Medicare Part D and Medicaid, if they find out that
2 that's happened in a case like this, they're going to ask for
3 their money back. And Janssen knew that.

4 They knew specifically because the claims that they
5 ended up resolving were for precisely the same conduct. They
6 knew that this was material to the government. They knew that
7 if they got caught, they would have to pay the money back.

8 And this was nationwide, ladies and gentlemen. This
9 was nationwide. Look at who we called in to testify:
10 Mark Wilhelm, Donna Graham, Sara Strand, Chrissy Brancaccio,
11 Matt Grooms, Jessica Penelow, Joseph Holshoe. Why? Why, if
12 what they were saying wasn't true, would they come into this
13 courtroom and testify about what happened years ago with this
14 company?

15 "The whole country was doing it, soliciting MIRs.

16 "What would have been your concern if somebody said,
17 hey, the Janssen rep left this study here?

18 "Well, that's illegal. I don't want to lose my job,"
19 Ms. Graham said.

20 This is about using off-label studies. It was common
21 practice throughout the country. Everybody felt under the gun
22 to perform.

23 Off-label promotion started happening at speaker
24 events.

25 "How many of these speaking events did you personally

1 attend?

2 "50 across the country," Sara said.

3 "What percentage of the ones you attended would you say
4 had off-label information discussed through a plant?

5 "I wouldn't want to guess at that. I'm not sure. It
6 happened frequently."

7 I mean -- and think about that. You know that you're
8 paying doctors to give speeches at these programs. And you
9 know that they're not supposed to go off-label. But you put a
10 plant in the audience to ask an off-label question, and now 20
11 other doctors get to hear about it. It's a good idea.

12 Why would a sales force want to do that? Why would the
13 sales representatives put plants in the audience? Why would
14 their managers encourage that? They were just going to be
15 able to sell this drug on-label for good uses in patients who
16 needed the drug. Why would you have to plant someone in the
17 audience to ask an off-label question? It's because they
18 couldn't sell enough of the drug on the label and they had to
19 go off-label. And that's how the sales representatives got
20 paid.

21 Mr. Wilhelm: "Yes, it was a nationwide scheme. Lots
22 of people involved, more than a hundred sales
23 representatives."

24 The scheme went on from 2006 until he left in 2010.

25 Ms. Brancaccio: "They told us. They gave us the

1 off-label information, the off-label studies. They told us to
2 go out to the doctors that we called on and use those studies
3 to talk to the doctors about Prezista and how it was lipid
4 friendly. Lipid neutral. Comparable to Reyataz." False,
5 false, false.

6 "We used those studies to go out in the field and talk
7 to doctors about it, and it came from Frank Murphy," who we
8 learned during the trial had been accused of doing exactly the
9 same thing by Joanne, by Joanne Cesario.

10 And that was substantiated because it was true. And
11 Frank Murphy kept his job, and Joanne Cesario didn't.

12 "Yes," said Ms. Penelow, "it would be basically either
13 Tony or Tim McSherry or Nancy Bartnett that was presenting.
14 They would go give out the off-label slides and presentations
15 to us to go out in the field."

16 "To your knowledge," Mr. Holshoe, different part of the
17 country, "based on your conversations with these people, what
18 went on in the district? Were they all selling these drugs
19 off-label?"

20 "From what we were saying, we were being pressured to
21 do that, yes.

22 "And based on your experience, was this limited just to
23 your district?

24 "No. Because, I mean, from national meetings, regional
25 meetings, everyone was saying it. Everyone was saying they're

1 getting put in this position but we've got to do this stuff.
2 But we know if we get caught doing it, we could lose our job,
3 or whatever."

4 Matt Grooms, different part of the country. "What were
5 they telling you was happening in districts across the
6 country?"

7 Same message. Same concern.

8 Did you get the impression that Matt Grooms was a
9 straight shooter? Didn't he just tell it to you like it was?

10 Same thing, same concern. Plants on speaker programs.
11 Get certain information out, if we could.

12 "Did other sales reps from different districts tell you
13 they were selling Prezista as lipid neutral or lipid friendly?

14 "Absolutely."

15 Now, Janssen is not going to be able to argue with
16 this, because who did they call? You know, at one point, they
17 were mocking Jessica and Christine for not calling enough
18 sales reps. How many do you have to call? Right? It's
19 Janssen. They have access to their former representatives.
20 Did they put a parade of witnesses on the stand to tell you
21 that this stuff did not happen? They put two people, one of
22 whom still works for the company, Tim McSherry, and Nancy
23 Bartnett, who just left.

24 She admitted that she would engage in off-label
25 promotion for a long time, if it turns out that lipid friendly

1 was not an approved message, and it wasn't. It was false.
2 Tim McSherry, he's at corporate now. He said shoulder shrug,
3 and that's who they called. That's who Janssen called to say
4 that this didn't happen.

5 Glen Mattes. "It's probable." Do you remember this?

6 "It's probable that issues related to off-label
7 promotion of Prezista and Intelence were brought to your
8 attention?

9 "Yeah, it's probable but not certain because I don't
10 recall.

11 "It's more likely than not?" I asked him.

12 "That's what probable means. Thank you for that
13 definition. My answer is probable but not certain because I
14 don't recall."

15 Off-label promotion, of course, it was brought to his
16 attention because it was part of the plan. It was part of the
17 plan.

18 Ms. Bartnett. Ms. Bartnett.

19 (Audio clip played at this time.)

20 Now, how long did we have to sit and listen to Janssen
21 cross-examine Ms. Brancaccio about why she had made one
22 recording? Over and over and over again attacked the
23 messenger, attacked the witness. You recorded Ms. Bartnett
24 with a doctor. Of course, if they didn't do that, what was
25 Janssen going to say? You're lying, Ms. Brancaccio. This

1 never happened. She records one time because Nancy Bartnett
2 goes off-label every time. And that's the message that was
3 being delivered to doctors over and over and over again.
4 Thank God Chrissy recorded that because they would deny it to
5 this day.

6 Causation. This is an interesting subject. Watch how
7 Janssen in this case defends itself by claiming things like
8 their marketing messages don't actually work. In real life,
9 of course, they know it does. We changed prescribing behavior
10 during speaker programs and on sales calls. Of course they
11 know it does. This is what they do for a living. They'll
12 parade somebody out here that they're paying to take the stand
13 to say, Nope. Didn't cause anybody's behavior to change.
14 We'll get to that in a minute.

15 Look at what the doctors were reporting back. These
16 surveys they conducted themselves: lipid neutral, QD dosing
17 gets the majority of attention for Intelence. Look how high
18 QD dosing was up on the radar. Of course that's what doctors
19 were saying because that's the message that was being
20 delivered over and over and over again.

21 Professor Sillup, he worked for Johnson & Johnson. He
22 carries the credo with him. He analyzed what was going on in
23 this case. He's the only pharmaceutical marketing expert to
24 have taken the stand, and he specifically said that their
25 off-label marketing caused physicians to prescribe Prezista

1 and Intelence off-label. Specific off-label messages caused
2 them to prescribe it for those reasons, and their off-label
3 messages directed at doctors had a lasting impact on their
4 prescribing behavior. This is not ice cream and shark
5 attacks. Right? Ice cream and shark attacks. No, it's not.
6 This is ice cream melting in the sun. Pharmaceutical
7 marketing works, and Janssen knows that, and they knew it
8 then.

9 Ms. Brancaccio would tell you she'd give off-label
10 messages and her numbers would go up. Ms. Penelow, We were
11 very aware. We put a plant in the audience. We were very
12 aware. Did it work? Sales went up and we kept doing it.

13 Mr. Grooms, delivering the lipid neutral message that
14 Prezista is comparable to Reyataz. Yes, it has some key
15 physician market shares that change.

16 "Do you remember any of your doctors that you called on
17 increasing their Intelence prescriptions after hearing the
18 once-a-day message?

19 "Yeah, Dr. Dietz and Dr. Todd, both."

20 He's giving you the names.

21 Sara Strand, same thing. The company started
22 disseminating off-label information.

23 "Did you see an impact on sales numbers?

24 "It was significant. I mean, I would guess maybe a 50
25 percent increase."

1 "Their marketing tactics, yes, I'm sure it's true."

2 This was Dr. Frank. Right. "I'm sure it's true that people
3 can be influenced without realizing it. It's not a really
4 difficult concept. Sure, yes."

5 And this is what Dr. Frank also said when we asked him,
6 "Would it surprise you, Doctor, to learn that many doctors
7 believe that others might be influenced but maybe not
8 themselves?"

9 "Everyone thinks that. I'm not going to be affected by
10 a sales rep. I'm not going to be affected by a sales call,
11 but those guys might."

12 Let's talk about the harm to the government as a result
13 of this scheme.

14 Kickbacks and off-label marketing. Janssen providing
15 kickbacks to speakers. Damages. That was all the speakers
16 for Prezista and Intelence prescriptions after their first
17 speech, after they were paid to be on this promotional speaker
18 bureau. That's what the law provides.

19 You get paid if only one purpose, if only one purpose
20 of Janssen's intent, if one purpose was to induce that speaker
21 or to reward that speaker for their prescriptions of Prezista
22 and Intelence, that's a kickback. And the damages that the
23 government suffers are their prescriptions because the
24 government reimburses for them. That's the law.

25 Off-label marketing. Janssen providing off-label

1 marketing to doctors. That's all the influenced doctors that
2 initiated, over attributed off-label Prezista and Intelence,
3 and that was what Professor Shaked testified to you about.
4 First thing that he did, he analyzed prescribing behavior.
5 Now, Janssen called Dr. Jena to try to suggest that perhaps --
6 well, they didn't suggest -- that perhaps professor Israel
7 Shaked somehow had it wrong. We'll talk about that later.
8 But the median ratio of non-speakers to speakers, look at the
9 typical doctor who is not a speaker and their off-label rates
10 compared to speakers. What does this tell you? Look at
11 compensation. Speakers who received more compensation
12 prescribe more than speakers who received less. Is that a
13 surprise? He's just analyzing their behavior, influenced
14 doctors who received contact from Janssen, their sales calls,
15 being attendees at a speaker program. The typical
16 non-influenced doctor compared to an influenced doctor, look
17 at the difference in their off-label prescribing rates. And
18 that's the story. Off-label marketing works.

19 Over and over and over again, Professor Shaked, who is
20 an expert in statistics, who has been teaching for 43 and a
21 half years, he studied the data; he analyzed it; he did it
22 right. Doctors who received more marketing contacts prescribe
23 more off-label Prezista and Intelence. And that's not a
24 surprise, is it? Stairstepped along the way, carefully
25 measured, each segment of contacts, the more times you're

1 contacted by a Janssen sales representative, the more times
2 you prescribe off-label for Prezista and Intelence.

3 So let's take a look at the kickback damages
4 calculation. It's not that difficult, ladies and gentlemen.
5 Once a speaker was paid those damages for the subsequent
6 prescriptions that the government reimburses for are damages
7 for kickbacks. That's how they're calculated. That's how it
8 works. There are 435,042 kickback claims that were submitted
9 for reimbursement to the government. Janssen will get up here
10 continually and say, Gosh, that's a lot of money. They made a
11 lot of money. \$3 billion in reimbursement. \$3 billion in
12 reimbursement from the federal government. This is 327.2 that
13 were tied -- 327 million that were tied to the speakers who
14 were paid cash.

15 Off-label damages. Take a look here. This is the
16 entire amount of money that the government paid for Prezista
17 and Intelence sales of \$2.9 million during this time period.
18 There are other off-label prescriptions, and off-label
19 prescriptions can be written by doctors, specifically for
20 their patients, but not if Janssen is responsible for
21 promoting off-label to those doctors. And that is what
22 Professor Shaked was careful to calculate for. \$446.7 million
23 in prescriptions written off-label by influenced doctors who
24 received Janssen's marketing, their sales calls and those
25 off-label claims submitted for reimbursement to the federal

1 government. There were 593,996 prescriptions reimbursed by
2 those doctors for those patients.

3 Now, Professor Shaked told you that he was excluding
4 certain segments, and these were conservative estimates,
5 because if there was any potential for overlap -- Prezista
6 treatment naive, Prezista lipids, Intelence treatment naive,
7 Intelence once-daily dosing -- look what he did. He just
8 eliminated the overlap. 16.4 million and 1.9 million for the
9 naive claims were enveloped in his total damages calculation.
10 He didn't double count. He was conservative. He estimated
11 downward.

12 Now, Medicaid pays 16 percent of these prescriptions
13 for Prezista and Intelence. It's actually closer to
14 17 percent, according to the data from Ian Dew that he
15 obtained from the federal government. These are Janssen's
16 documents, at the time, for both Prezista and Intelence.

17 There are kickback damages and off-label damages but
18 there's overlap, okay, because some doctors wrote off-label
19 prescriptions and they were receiving kickbacks. So where
20 there was overlap, Professor Shaked excluded those from the
21 total. That's \$84.8 million that were taken out of the
22 damages total.

23 \$327.2 million for kickbacks, \$361.9 million in
24 off-label damages. That's a reduction of \$84.8 million and
25 112,731 claims.

1 Now, there's something that is super important to
2 mention about this. The patients get their drugs. They keep
3 them. It's not -- it's no suggestion that anybody's got to
4 return the medications they received. The focus is on Janssen
5 and their conduct and the amounts of money they improperly
6 received from us, from the taxpayers. It's time to return
7 that money.

8 So when you have the opportunity, the off-label damages
9 are as follows: 300,377,000, that's 481,265 claims. And the
10 Medicaid damages, 17 percent as supported by the data from --
11 from Ian Dew as calculated by Professor Shaked, that's
12 17 percent of the total. 61,523,000. 300 million 377,
13 61 million 523, federal, Medicare and ADAP, state Medicaid.

14 The anti-kickback damages, federal damages of
15 271,576,000. That's 435,042 claims. The state damages
16 associated with that, the Medicaid damages, the 17 percent
17 paid by Medicaid 55,624,000.

18 Let me tell you about Dr. Jena very quickly. This was
19 Dr. Jena's first False Claims Act case. He's the one that was
20 out there and said Professor Shaked made an error. You can
21 imagine our heads were, like, on that one, because, first of
22 all, this gentleman has never seen a causation analysis
23 performed by somebody who's trying to get money back for the
24 government that he believes satisfies his test. The problem
25 with it, ladies and gentlemen, is that nobody told him what

1 the right legal standard was. And you're about to be
2 instructed on what that standard is in a False Claims Act
3 case.

4 Remember he said you have to -- for him to be satisfied
5 that causation happened, the improper influence caused the
6 damages to the government, well, he said -- he was applying an
7 economic theory on causation, and if it doesn't match with
8 ultimately the standard that you're going to be asked to
9 apply, it's irrelevant. It's possible he got the wrong legal
10 standard.

11 So as I understand it, you say that you have to get
12 records, sales call by sales call, doctor by doctor, patient
13 by patient, chart by chart, prescription by prescription and
14 figure out why each prescription was written across millions.
15 That's what he took the stand to tell you was the standard in
16 a False Claims Act case. That's just false. Nobody could
17 ever do that, and companies like Janssen would get away with
18 it. It can't be done.

19 Now, what you do is what you did -- he said, I think
20 that's how I described as the gold standard. Of course
21 Janssen's expert is going to say that. You can't catch me.
22 You can't prove it.

23 He says, "Those are kind of prerequisites. That's what
24 you need before you start seeing any differences in
25 prescribing between one group and the other is a hundred

1 percent because of the conduct."

2 A hundred percent. Even criminal cases have a
3 reasonable doubt standard. What kind of standard is proving a
4 hundred percent that A caused B? Do you need to know? Does
5 it strike you as fanciful that marketing and payment of cash
6 causes people to change their prescribing behavior? It's not
7 a remarkable concept. You all knew that when you first took
8 your seat on the jury.

9 And guess what? They gambled. So confident were they
10 in this doctor, the economist who took the stand and applied
11 the wrong legal standard to the facts of the case, that he did
12 not tell you, No, if I'm wrong on causation, here's the amount
13 of damage to the government. It's lower than
14 Professor Shaked's. It's not quite 300 million. It's 200
15 million or 100 million.

16 No. He didn't do that. Unbridled arrogance by
17 Janssen.

18 There is no evidence in the record other than
19 Professor Shaked's calculations as to what the damages are to
20 the government payers because Janssen decided to roll the dice
21 on Dr. Jena.

22 What he had done, by the way, to increase the race, he
23 tried to show that the two groups were the same in prescribing
24 habit: The noninfluenced and the influenced.

25 And we got Professor Shaked back on the stand. Do you

1 remember that? He was, like, "Yeah, he came back with his
2 report and all of a sudden, the two groups had the same
3 levels. The noninfluenced doctors and the influenced doctors,
4 had the same rates of prescribing off-label."

5 He said -- Professor Shaked said, "How is that
6 possible?"

7 Then he went and he looked, and he found a tiny
8 footnote in Dr. Jena's report. And Dr. Jena had excluded
9 thousands and thousands of doctors from the denominator. He
10 changed the ratio. He worked backward to get the ratio up and
11 the noninfluenced physicians. He rigged the results so it
12 would look like there's nothing to see here.

13 And Professor Shaked said, "That's like saying if
14 you're comparing downtown Los Angeles to Beverly Hills and you
15 decide to say, okay, what are the cars like that people buy,
16 but you just ignore all the secondhand and used cars. You
17 take them out of the equation. Obviously Los Angeles,
18 downtown, is going to look a lot more like Beverly Hills when
19 you get rid of all the used cars."

20 That's what Dr. Jena did. And it was the difference
21 between the statistician and Professor Shaked and a magician
22 who tried to make damages disappear.

23 Now, you'll hear from Janssen. You'll hear their
24 defenses. No doubt they know the government doesn't pay for
25 kickbacks or off-label. Ms. Kaucher was asked, "Do you

1 understand Medicare Part D to be the portion of Medicare that
2 reimburses for prescription medications?"

3 "I do."

4 And that would include drugs like Topamax, Risperdal,
5 Prezista, and Intelence, all in the protected classes, and
6 they knew that they would have to pay the money back because
7 twice before they did. 2010, 2013, two protected drugs,
8 Topamax and Risperdal.

9 Guidance documents. Their own guidance documents.
10 Look what it says about Part D. I anticipate that you're
11 going to hear some shake 'n bake from Janssen when they come
12 up here. They're going to make this argument, we've all seen
13 the little diagram on the screen where there's reimbursement,
14 little sales rep, and then there's a -- I think there's a
15 Part D plan sponsor. And it's their argument that somehow
16 that Part D plan sponsor, an insurer who works for the
17 government, is somehow going to let them off the hook.

18 Not sure what the theory is, but that's their argument.

19 Their own guidance document that -- when we went into
20 the data, Ms. Kaucher was the one who had edited it, says,
21 "Look, Part D is rife with potential fraud and abuse.

22 "Why?

23 "Because these are. Certain drugs are in protected
24 classes, and we do, as a nation, want patients to have them.
25 We want them to have them."

1 So it's easier for companies like Janssen to get
2 reimbursed for those drugs. But when the government finds out
3 about it, they always have to return the money. And that's
4 why we're here.

5 And they know, this is Janssen's own document, that you
6 cannot incentivize doctors to prescribe medically unnecessary
7 drugs. And that's the key language. This is in their own
8 guidance document. It is medically unnecessary to prescribe
9 Prezista for a patient with a lipid issue. It is unnecessary
10 and unreasonable to give that patient that drug. Why?

11 Dr. Glatt told you. There are safer alternatives.
12 Reyataz was available. And there's only one witness who
13 testified about that subject: Dr. Glatt. It is medically
14 unnecessary, medically unreasonable to give that patient that
15 drug. It violates the standard of care.

16 And every time they push an influenced doctor and they
17 pushed these messages on a doctor, that's what's been
18 calculated in this case. It was a medically unnecessary,
19 medically unreasonable prescription from an influenced
20 physician who had been receiving their promotional messages.
21 That's the money they had to return.

22 Protected class is not a license for fraud. If you get
23 paid and it turns out that you violated the Anti-Kickback
24 Statute, or you violated the False Claims Act by engaging in
25 off-label promotion, you're going to get caught, and you're

1 going to have to give the money back. And, ladies and
2 gentlemen, that's you. That's what we're going to be asking
3 you to do.

4 Dr. Glatt specifically told you about this. Look,
5 Risperdal was an antipsychotic. Topamax was an
6 anticonvulsant. Why did we ask him those questions? Because
7 Janssen knows those are two drugs in two protected classes,
8 the six classes like the HIV medication.

9 And they knew it doesn't matter if you're in a
10 protected class as a pharmaceutical manufacturer. If you get
11 caught, you've got to pay the money back.

12 Glen Mattes was asked, "You're aware of the fact that
13 there were allegations brought by whistleblowers about Topamax
14 that resulted in a corporate integrity agreement that Janssen
15 entered into with the federal government, correct?

16 "Yes."

17 Mr. Mattes was overseeing Topamax before he moved on to
18 Janssen Tibotec.

19 "You don't know that they're medicines that the company
20 makes?

21 "Well, I know about Topamax and Risperdal." That was
22 Virginia Evans, the subject of these two Corporate Integrity
23 Agreements.

24 Let me take a minute to talk about compliance. Another
25 defense that we thought, and it proved out to be true, that

1 Janssen was going to take. Look at all our pretty documents.
2 We have these compliance documents, and we've all seen them up
3 on the screen throughout the course of this trial. You may
4 not do this. You shall not do this. You shall report. Do
5 not disclose. Do not share. Careful communications. Watch
6 out for emails. They might end up in the hands of the
7 government or us. That's what they wrote.

8 That's what compliance was in this organization.
9 Nobody could figure out who the compliance officer was from
10 2006 to 2010. We still don't know the answer. Dr. Patel says
11 it wasn't him. We don't know. It was an organization running
12 by itself.

13 And then Ms. Kaucher, well, she took the stand and she
14 told you what she told you about Joanne Cesario. We didn't
15 ask her those questions. Do you remember that? I didn't ask
16 her those questions. It was Ms. Brown.

17 "Tell us about Joanne Cesario.

18 "Well, I went and did this investigation and it was
19 unsubstantiated. Nothing happened off-label. Nothing,
20 nothing, nothing.

21 Okay, really? Go show us those investigation
22 documents. Where were they?

23 Comes back later, "Well, I didn't really remember. I
24 was testifying from memory. Some of them were substantiated.
25 Some of them were not." Unbelievable.

1 This is an important persuasion technique. See,
2 because in this case, the way that Janssen has defended
3 itself, from our perspective, it's a microcosm of the way that
4 they distributed their promotional messages, their misleading
5 messages out in the marketplace. They've just adopted that
6 for the courtroom, in our view.

7 That's what gaslighting is. It's the kind of
8 persuasion. You all probably know somebody who can do it to
9 you. Somebody in your family maybe, some of your friends.
10 Hopefully not. Hopefully not. But it's a style of
11 communication that makes you start to really doubt yourself.
12 Makes you start to wonder, Hey, wait a minute. Maybe I'm the
13 one who's in the wrong. Maybe we're doing things wrong. They
14 flip things around, and they put it back on you. That's the
15 tactic of gaslighting. It makes you doubt your sanity.

16 "Practice of grossly misleading someone, especially for
17 one's own advantage." Well, what happened to Ms. Brancaccio
18 right before this trial started? Right? You saw in opening,
19 this is -- I mean, this is from their opening statement,
20 Janssen's opening statement:

21 "I thought I heard counsel in opening, Ms. Penelow and
22 Ms. Brancaccio, describe you all as former employees of
23 Janssen. But what you're going to hear, and what the evidence
24 is going to show, is that Ms. Brancaccio is actually still our
25 employee today."

1 That's from Janssen's opening statement.

2 On April 26th, two weeks before the trial had started,
3 they had fired her. They had sent her a letter saying, You're
4 fired. And if you want any severance, sign this document, get
5 a hundred thousand dollars and release all your claims.

6 12 years in preparation for this trial, Chrissy
7 Brancaccio took the stand and told you everything that
8 happened while she was there. And what is Janssen doing in
9 the background? They're sending her a letter. They're firing
10 her. And if she wants a hundred thousand dollars in
11 severance, she's got to release her claims.

12 In the middle of trial, they send her a take backsie.
13 Okay. Whoops. Maybe we'll change our mind. They send her
14 another letter.

15 And then they get up in opening statement and tell you
16 she's an employee, after they fired her. Who does that? This
17 company does. This company who has been defending this case
18 while Ms. Penelow and Ms. Brancaccio have been sitting there
19 the entire time, while you have been sitting, ladies and
20 gentlemen, listening to the evidence coming from that witness
21 stand for five weeks, where is Janssen's executive? Where is
22 Johnson & Johnson?

23 One of the things maybe you didn't see here, in
24 whistleblower cases -- look, at some point they told you, No,
25 you didn't have to give up your rights, Ms. Brancaccio.

1 That's not true. She was going to have her waiver of rights
2 to this case in exchange for a hundred thousand dollars.

3 Here's another example. All right. And this stuff --
4 look, I know you saw us jumping up and passing each other
5 Post-its the whole time and typing furiously on our computers,
6 and we're sorry for that. It's exhausting. It is exhausting
7 to keep up with a company that will do anything to mislead,
8 and we wanted to make sure that didn't happen.

9 That's why my colleagues and I were passing each other
10 notes the whole time. That's why Ms. Wendel was keeping me on
11 my toes. Anytime that something would be brought up, we would
12 find the truth, and we would come up and we would fix it.

13 But this is just a perfect example. There was
14 Professor Sillup sitting on the witness stand. He's giving
15 you, as a former Johnson & Johnson employee, as an expert
16 witness who teaches pharmaceutical marketing, who has taught
17 for years, he's telling you all about the techniques that
18 Janssen used in this case. And in his report, he cites 82
19 articles, academic literature. One was from this doctor.

20 She doesn't like pharmaceutical representatives because
21 they have an undue influence on doctors. That's what she's
22 learned. And so they play a TikTok video of this doctor to
23 convince you that somehow she's of bad character and,
24 therefore, somehow that makes Professor Sillup less credible
25 for citing to her Washington Post article. That's -- I mean,

1 that's how the logic went.

2 It's one of those attack, attack, attack Professor
3 Sillup.

4 Well, what actually turned out? You hear from
5 Dr. Jena, and he's coauthored an article for her, their own
6 expert. Their own expert has coauthored an article with that
7 doctor. Complete waste of your time. We have no idea why we
8 were talking about it, but they're trying to use psychological
9 techniques on you to make sure that everybody who takes that
10 stand to tell the truth is somehow deemed not credible.
11 That's what that was.

12 How about this one? For years, for years the Relators,
13 we were trying to get those Joanne Cesario documents. Nope.
14 Janssen withheld them.

15 But what does Janssen do? See, Ms. Penelow, she's
16 really close to her mom. And she was having private,
17 privileged communications with her lawyers, right? She was
18 having private communications with her own lawyer, Ms. Joy
19 Clairmont of Berger & Montague back in 2012, as she was
20 getting ready to file this case. But because she sent the
21 email to her mom, no longer privileged and Janssen gets ahold
22 of it.

23 And so what do they do with this email between
24 Jessica's lawyer and Jessica? They come up here and they try
25 to insinuate that this was all a work and fabrication, a

1 product of lawyers. And they cross-examine her on it.

2 They're asking her questions about a private email.

3 Now, here's what I will tell you. This is the kind of
4 email that makes me proud to be a lawyer and practice with
5 people like Joy Clairmont. Look at what she actually put in
6 the email. Is this the kind of thing that you would want a
7 lawyer who represented you to ask you? Please, this is what
8 they're doing. They're drafting the complaint in this
9 lawsuit, and Janssen got a hold of it and somehow it's going
10 to be bad.

11 "Read for accuracy and completeness. If we've gotten
12 any facts wrong or omitted anything important, please let us
13 know. You can write your comment directly into the
14 complaint." That's what you want a lawyer to do. Be
15 accurate. Be complete.

16 "Fill in the blanks if you're able. You will see
17 questions throughout the document that are highlighted in
18 brackets or bubbles."

19 And over and over and over again, the insinuation was
20 the lawyers had manufactured the claims. The lawyers.

21 That's the kind of thing that you want lawyers to do:
22 Be accurate, be complete, tell the truth. And somehow Janssen
23 decided to turn that against Ms. Penelow. That's gaslighting.

24 What about Sara Strand? Do you remember this exciting
25 moment when Ms. Strand was testifying about what had taken

1 place over the course of years and years and years while she
2 was at Janssen, and then she was attacked for supposedly
3 deleting documents. Something that has nothing to do with
4 off-label marketing that she was overseeing and confessing and
5 telling you took place.

6 "You went into your deposition, and you told us your
7 documents were deleted." No, she didn't. She took her
8 documents to the deposition and turned them over. She
9 actually turned them over in her deposition.

10 And why were we being put through that if it's because
11 after her testimony they have to spring up and attack the
12 messenger and put them back on their heels, and then maybe you
13 all will think that a day and a half of Sara Strand telling
14 you what's going on at Janssen was somehow not credible, and
15 that's the technique?

16 What about this one? You went to her wedding. You
17 went to dinner with this person. These people from across the
18 country who worked together are somehow all connected in some
19 scheme to tell some story that is not true. Does that seem
20 right to you guys? Does that seem right to you, ladies and
21 gentlemen? That people from all across the country, from
22 years ago, are going to fly into court, no connection to the
23 Relators, no financial interest in the case, they're going to
24 take a witness stand and they're going to tell a story in that
25 detail about what took place at this company because one of

1 them went to the other's wedding years ago. That's the
2 technique that Janssen has employed in this case.

3 It's not about Facebook and wedding pictures and TikTok
4 videos. It's about kickbacks and off-label marketing.

5 Now, what did Ms. Kaucher tell us when she took the
6 stand? And remember this? "I was not able to substantiate
7 any of the claims that she had made by any factual substance."
8 That's sworn testimony from Ms. Kaucher, the compliance
9 officer for Janssen, to you, under oath, on the stand. Just a
10 few weeks ago.

11 What happened? We asked her, Mr. Wirmani asked her,
12 "Did you know that, since your testimony last week, we learned
13 that Janssen withheld the documents relating to those
14 allegations? Are you aware of that fact?"

15 She said, "I wasn't aware of that."

16 Allegation, substantiated. Allegation, substantiated.
17 Why would they withhold documents, put a witness on the stand,
18 tell you a story about Joanne Cesario and then think that they
19 wouldn't get found out? We're not going to miss it. We have
20 been chasing it for a long time. But they did it anyway.
21 Because if they can get something past you, they'll do it.
22 Because they really don't want to pay the money back. They
23 really don't want to pay it back.

24 And you can assume, as the Court has instructed you, in
25 your instructions, that they withheld those documents, they

1 withheld those documents concerning another employee's
2 allegations of off-label promotion of Prezista and Intelence
3 because the evidence was unfavorable to Janssen. And that's
4 probably obvious to you. But who does that in a case like
5 this? That's what we're dealing with.

6 A funny thing happened while Ms. Graham was on the
7 stand. Janssen was trying to cross-examine her over one part
8 of one sentence of a 28-page, multiple-paragraph declaration,
9 a sworn statement that she had made years ago in this case,
10 and they decide it was going to be a good idea to
11 cross-examine her on one sentence and then they put her
12 declaration into evidence. That's Defendants' Exhibit -- we
13 didn't put it into evidence. We can't. But they can, and
14 they did, I think, by accident. It's Defendants' Exhibit
15 8560, Janssen's exhibit, Declaration of Donna Graham. You
16 want to take a look at it when you're back there deliberating?
17 It's got all the receipts, all the names, everything that took
18 place in one document, just from Donna Graham.

19 Now I'm going to talk to you about the jury
20 instructions that you're going to receive from His Honor. I
21 want to talk to you a little bit about the law. If you'll
22 just bear with me, I'm sure you're hungry and tired, and I'm
23 sorry for that. I drew the black bean on timing. Okay. I
24 apologize for that.

25 But if you'll just bear with me because this is really

1 important.

2 This is a civil case, as His Honor instructed you.
3 That means it's a preponderance of the evidence case. Not a
4 Dr. Jena-100-percent case. That's not what this is. It's a
5 civil case where if the Relators prove that something was more
6 likely than not. More likely than not. If the scales tip
7 slightly in the Relators' favor, then you have to rule in the
8 Relators' favor. That's the standard. It's a civil case.
9 Okay. Not reasonable doubt. It's not a criminal case. It's
10 not whatever standard Dr. Jena thought was applicable.

11 But the reason that's important -- of course we think
12 the evidence has been overwhelming in this case. That's why
13 we have taken our time to show you the story, document by
14 document, witness by witness, brick by painful brick. We
15 wanted to overwhelm you with the evidence because, otherwise,
16 they will stand behind the doctors who they were paying and
17 make it seem like we're attacking doctors and make it seem
18 like we're being unreasonable and unfair to Janssen, and they
19 will walk out of this courtroom and they will laugh. We're
20 not going to let that happen. It is a preponderance of the
21 evidence standard. Janssen violated the False Claims Act.
22 "Did Relators prove by a preponderance of the evidence more
23 likely than not that Janssen violated the federal False Claims
24 Act by unlawfully promoting Prezista or Intelence?" Do you,
25 ladies and gentlemen, you'll be asked, when you're

1 deliberating, feel like we've proven that that was more likely
2 than not?

3 For you to find that Janssen's liable, we have to prove
4 the following evidence more likely than not: falsity,
5 causation, scienter, their intent and materiality, important
6 to the government.

7 Falsity, you're instructed that it's false, right, to
8 make a claim to a federal health care program. It's false if
9 it seeks reimbursement for a prescription that's not eligible
10 for reimbursement. And, look, this is where Dr. Jena lost the
11 script. This is where it would have been helpful for him to
12 find out what the standard actually is in a civil False Claims
13 Act case before he came in here and gave you his testimony on
14 how he couldn't prove it, right?

15 Janssen caused preponderance of the evidence, more
16 likely than not, slightly greater than 50/50 that Janssen
17 caused claims to be submitted to the government a substantial
18 factor, a substantial factor in inducing providers to submit
19 claims for reimbursement. So you have defined that it's more
20 likely than not that Janssen's conduct was a substantial
21 factor. Not beyond a reasonable doubt, not the only thing,
22 right? Just a substantial factor in inducing providers to
23 submit claims for reimbursement. And that's what Dr. Jena had
24 no clue about, the standard in a case like this. You just
25 have to think, was it reasonably foreseeable or anticipated as

1 a natural consequence of Janssen's conduct off-label promotion
2 leads to off-label prescriptions being submitted to the
3 federal government? That's it.

4 They knew because they know. State of mind.
5 Knowingly. They had knowledge, they acted with deliberate
6 ignorance to the truth or falsity or they recklessly
7 disregarded the truth. If we haven't proven that, I don't
8 know how it can be done.

9 Materiality. How many documents did we put up on the
10 screen showing you how important this type of misconduct is to
11 the federal government in Janssen's own documents, in their
12 own compliance manuals. Their president, Mr. Mattes, admitted
13 it. Mr. Iacobellis admitted it. Every single witness who was
14 confronted, Is this important to the government? Does it
15 matter to the government? Of course it does. And these
16 claims are being brought on its behalf. And Janssen will get
17 up there and tell you, Well, they're still paying claims.
18 They're still paying claims for these drugs. Yeah. No
19 kidding. Because this case enforces this law. And then if
20 they're found liable, they will have to give the money back.
21 That's what this case is.

22 "Did Relators prove by a preponderance of the evidence
23 that Janssen violated the federal False Claims Act by
24 unlawfully promoting Prezista or Intelence?" Ladies and
25 gentlemen, we would ask you to find yes.

1 "What number of false claims" -- this is the
2 prescriptions submitted to the government for reimbursement --
3 "what's the number of claims" -- it's just something that
4 you're asked in a False Claims Act case -- "that Janssen
5 caused to be submitted?" 481,265.

6 What amount of damages, if any, did Relators prove by a
7 preponderance of the evidence, it's more likely than not, that
8 the United States, the federal government, suffered as a
9 result of that conduct that you found in that question?
10 That's the reduced damages amount. That's only for Medicare
11 and ADAP, the AIDS Drug Assistance Program, federal funding.
12 300,377,000, 300,377,000 is what we're asking you to return to
13 the government.

14 Janssen violated the Anti-Kickback Statute. "Did
15 Relators prove by a preponderance of the evidence that Janssen
16 violated the federal False Claims Act by violating the
17 Anti-Kickback Statute?" Members of the jury, we're going to
18 ask you to find that the answer to that question is yes.

19 Here is the special verdict form, and this is -- these
20 are the elements of the actual claim. You have to find that
21 Janssen offered or paid remuneration. Nobody can say that
22 word, by the way. None of us can get it right. Every single
23 time we mess it up, but it's including a kickback directly or
24 indirectly, openly or secretly, in cash or in kind. Well,
25 they did it openly. They paid in cash. They also wine and

1 dined at fancy restaurants for their influence. That one
2 purpose, just one purpose, right, not the purpose, not the
3 only purpose, not a substantial purpose, not the primary
4 purpose, just one purpose was to induce or reward
5 prescriptions of Prezista or Intelence. That's the standard.
6 That those claims for payment were submitted to a federal
7 health care program and they did it knowingly and willfully.
8 That's the standard.

9 Remuneration has been defined for you. Of course, it's
10 anything of value, cash, in kind, or covert. It is not a
11 defense that there might have been some other reason:
12 education, experience, wanting to be nice, nope. That's not a
13 defense. If you think it's more likely than not that Janssen
14 was paying money to these doctors to induce or reward them for
15 their prescriptions, they're liable under the Anti-Kickback
16 Statute, and they have to return the money.

17 Payments for prescriptions were submitted to a federal
18 health care program, and there was some evidence of a link,
19 just a link between those prescriptions and their payments, a
20 link in the conduct. Their payments to doctors, doctors write
21 prescriptions, the prescriptions get submitted to Medicare,
22 Medicaid, and ADAP. It's that simple.

23 And that's for federal health care programs. They did
24 it knowingly and willfully. Of course they did. All right.
25 They knew from the beginning they could get caught and they'd

1 have to do this. They've done it before. They knew it was
2 material to the government.

3 And you know that, if you submit a claim to the federal
4 health care program that is false, if it seeks reimbursement
5 for a prescription, that's not eligible for reimbursement.
6 We'll talk about that in a minute. Did Relators prove by a
7 preponderance of the evidence that Janssen violated the
8 federal False Claims Act by violating the Anti-Kickback
9 Statute? We hope you answer that one yes. It has been a long
10 time coming.

11 What number of claims are relating to the Anti-Kickback
12 Statute? That's the prescriptions written by doctors and
13 attributed to those doctors for the payments to the speakers.
14 That is just 435,042 false claims as a result of speakers who
15 are paid by Janssen, the \$17 million that they put in their
16 pockets.

17 What amount of damages are associated with the
18 kickbacks? Well, it's 217,576,000 to the federal government.
19 And then with respect to the state governments, that's
20 Medicaid, that's 17 percent of the 327 million.

21 You're going to be asked to find that each one of the
22 state government False Claims Acts was violated as well,
23 ladies and gentlemen, and they're the same standard as the
24 federal False Claims Act. You're just going to be asked to
25 find liability with respect to those states under the same

1 standards. We're going to ask you to find yes as to those
2 states as well so that they get their money back from
3 Medicaid.

4 And you'll have to go through them one by one, but
5 thank you for doing that.

6 "What amount of damages, if any, did Relators prove by
7 a preponderance of the evidence that the states sustained as a
8 result of any violations you found in that question?" That's
9 the 17 percent of Medicaid. 17 percent of the 327 million.
10 61,523,000 back to Medicaid.

11 Did Relators prove by a preponderance of the evidence
12 that Janssen violated the state False Claims Acts for any of
13 the following states by violating the Anti-Kickback Statute?
14 You have to find it for the states as well.

15 We'd ask that you do so.

16 What amount of damages did Relators prove by a
17 preponderance of the evidence that the states sustained?
18 55,624,000. That's Medicaid.

19 You can take into account Janssen's knowledge. You can
20 take into account its plan. How many times did they get up
21 there -- and this is really important because you'll see this
22 in the instructions. How many times did they get up there and
23 say, is it even possible, Mr. Iacobellis, is it even plausible
24 that a nationwide scheme to promote off-label was taking
25 place? Would it even seem like that's possible? They said

1 that over and over again with their witnesses.

2 No, it's not possible.

3 Of course it's possible. They're just putting the same
4 playbook in place. They know it's possible because they have
5 two Corporate Integrity Agreements in place, two separate
6 times for doing the same thing. And you can take a look at
7 those. The instructions tell you what you can take into
8 account with respect to those, the evidence you can consider.
9 They had the motive, the opportunity. They acted with an MO;
10 they acted with a pattern, a method of operation. Paying
11 speakers kickbacks, engaging in off-label promotion of these
12 drugs. It wasn't a mistake, and it wasn't an impossibility.
13 That's what that's all about.

14 And you can consider that for whether the government
15 would consider this conduct to be material. Of course it is.

16 Think about the withheld documents, ladies and
17 gentlemen, and why somebody in a case of this magnitude would
18 want to keep information from being turned over to the other
19 side. Again, this is like ice cream melting in the sun. This
20 is like off-label marketing causes off-label promotion.

21 One thing I'm going to ask of you before I close -- I'm
22 going to have one last opportunity. We are the plaintiff, the
23 Relators. We have the burden of proof. Preponderance of the
24 evidence. So I get to speak to you now, and then when Janssen
25 speaks to you, I'll get to come back for a little bit

1 afterwards.

2 But I would like for you to think about one thing.
3 There is going to be a "the rest of the story" argument made
4 to you by Janssen. It's going to be, in my mind, and by my
5 estimation, filled with a lot of the same maneuvers that
6 Janssen employed during this case. Attacking the witness.
7 Attack, attack, deny, deny.

8 Pay attention if you hear any ounce of acknowledgment
9 or contrition for what they did. My prediction is you won't.
10 That's our prediction.

11 Thank you for your time. I look forward to speaking to
12 you again.

13 THE COURT: Thank you, Mr. Marketos.

14 Folks, we're going to break for lunch. I'm going to
15 give you an hour lunch break, and then we will reconvene with
16 closing argument from Janssen.

17 With that, let's get the jurors for their break. And I
18 appreciate your attention.

19 One other thing, just as a reminder. Do not discuss
20 this case. You are not in deliberations until I instruct you
21 to be there. I've given 99 percent of the instructions, but I
22 am holding one instruction back, which is your deliberations
23 process. You get that right before you begin deliberations.
24 Don't discuss the case while you're at lunch.

25 Thank you.

1 THE DEPUTY COURT CLERK: All rise.

2 (The jury exits the courtroom.)

3 THE COURT: Everybody have a seat.

4 Anything we need to address before we adjourn for
5 lunch? Although I know that you're going to come back before
6 the hour so we address those documents that Janssen was
7 looking to admit.

8 No?

9 MR. MARKETOS: Yes, Your Honor. Thank you.

10 THE COURT: Mr. Wyatt.

11 MR. WYATT: I'm sorry, but, yes, one quick thing.

12 Accusing the opposing counsel of gaslighting, which is
13 what just happened here over multiple slides in a very
14 premeditated way, is completely improper argument. It is
15 accusing the other side, and counsel in particular, of
16 deception, which is beyond the bounds of reasonable argument,
17 and it also violates the Rules of Professional Conduct.

18 So I don't know what remedy we're seeking, but that is
19 completely inappropriate argument. And at the very least, I
20 would appreciate an instruction from the Court that we should
21 not hear that again in rebuttal.

22 THE COURT: Is there any reason why the objection was
23 reserved until now?

24 MR. WYATT: I didn't want to draw attention to it in
25 front of the jury, Your Honor. And to be honest, I think it

1 goes beyond jury argument. Attacks on the opposing counsel
2 are just fundamentally inappropriate.

3 THE COURT: Mr. Marketos?

4 MR. MARKETOS: Yeah, excuse me. Your Honor, I'm not
5 going to be beaten back by Mr. Wyatt. The technique that
6 they -- Janssen -- has used is attacking our clients
7 throughout the case. That is the technique we were talking
8 about. That is closing argument.

9 Describing the techniques that they used to defend the
10 case, I didn't say one word about Ms. Brown. That is the
11 technique that they used to attack our clients. This is
12 closing argument, and you don't get to feign indignation with
13 me in a closing argument. That is what they did to our
14 clients. And I'm entitled to show the techniques that they
15 used to defend themselves in the case and attacking the
16 messenger.

17 THE COURT: All right. I'll take it under
18 advisement.

19 What was the remedy you were asking for anyway,
20 Mr. Wyatt? Since you didn't object during it, you waited for
21 the end of it.

22 MR. WYATT: I'm sorry, Your Honor. I wanted an
23 instruction not to do that again in rebuttal. And I
24 respectfully and strongly disagree with the notion that
25 calling somebody a gaslighter, which is what happened -- and

1 Ms. Brown was not mentioned by name, but counsel was
2 referenced.

3 That is not the same as addressing tactics. If you
4 want to say their defense was to attack the credibility of
5 witnesses instead of point to the evidence, that's fine. That
6 is ordinary argument referring to techniques. But gaslighting
7 is different. That is accusing the counsel of having an
8 improper motive and being deceptive toward the jury, and that
9 is completely improper.

10 THE COURT: All right. Mr. Marketos, do you have
11 something else you want to say? I mean, I'll take this under
12 advisement. We're going to address it after you all get some
13 food in your stomachs and maybe you'll be less cranky, but you
14 tell me if you want to put anything else on the record for
15 now.

16 MR. MARKETOS: I have plenty more to say to that,
17 Your Honor. I have plenty more to say about it. I've never
18 heard somebody feign indignation over our criticism in closing
19 argument of the manner by which a client defended a case.

20 THE COURT: All right. I've heard you both. I'll
21 take it under advisement. I haven't put any thought to it, to
22 be candid with you. There was no objection made during the
23 close. I understand that you waited until after. I'm not
24 saying it's untimely. I can see why, as a tactical measure,
25 you might wait to interrupt a closing, but let me consider

1 what you've all said, and we can address it after you guys
2 come back from the lunch break.

3 But your remedy is to instruct counsel on not using
4 that terminology?

5 MR. WYATT: Yes, Your Honor. I don't want the jury
6 to be reminded of this terminology. And sorry. Just for the
7 record, my indignation is not feigned. I think that should be
8 apparent --

9 THE COURT: I understand. There was argument, right?
10 You're saying it's not; he says it is. You're both making
11 argument for the Court.

12 So look, I'll take it under advisement. We can talk a
13 little bit more about this after you return from the lunch
14 break.

15 Have you guys conferred on the documents yet? Is there
16 still an impasse on the admission of the two batches of
17 documents that Janssen was requesting to move in?

18 MR. MARKETOS: Your Honor, obviously with a special
19 verdict, we haven't even gotten to go through them yet, but
20 we'll do our best.

21 THE COURT: So why don't you all do that and then let
22 me know if we still need to address those issues. If so -- so
23 what do you think? Are you going to come back in 30 minutes
24 or 40 minutes?

25 MR. MARKETOS: I'm going to have to go one by one.

1 THE COURT: Why don't you all return in 40 minutes.
2 That gives me 20 minutes to resolve these issues, which I
3 don't think I'll need more than that. And if the jurors need
4 a little bit longer, well, then, they can enjoy their
5 cannolis.

6 All right. So that's how we're going to deal with
7 this. So I'll see you back in 40 minutes.

8 But we only have two issues before me, those documents
9 that I need to make a decision on, what's before me and
10 whether they're admissible or not; and then, secondly, I'll
11 take under advisement with some maybe limited continued
12 argument on Mr. Wyatt's objection to the closing, and we'll go
13 from there.

14 Thank you all. You may be seated. We're adjourned for
15 lunch.

16 (Luncheon recess was taken from 1:20 p.m. until 2:00
17 p.m.)

18 THE DEPUTY COURT CLERK: Remain seated. Court is now
19 in session.

20 THE COURT: All right, folks.

21 What are we talking about? Are we going to talk about
22 evidence first or -- let's talk about one issue at a time.

23 Have you been able to look at the documents,
24 Mr. Marketos, that Janssen is looking to admit?

25 MR. MARKETOS: Yeah, some of them, Your Honor. There

1 are a number that aren't on the exhibit list. We've tracked
2 down the Bates numbers for those that we can.

3 And forgive me, Your Honor, absolutely not. They're
4 trying to get in, like, CMS final rule documents that they
5 were going to try to get in through their expert but that
6 expert they didn't call. You know, CMS-related documents.
7 One that's got the language in it that they think that, you
8 know, reasonable and -- it's just -- it's long legal
9 documents.

10 Absolutely not. They're trying to dump documents. In
11 fact, I don't know if Your Honor has seen the length of the
12 list, but the documents themselves are lengthy, and in our
13 view, it's an attempt after the close of trial to get
14 documents in that they didn't put in through the witness --

15 THE COURT: That you also couldn't address in your
16 closing.

17 MR. MARKETOS: Exactly.

18 THE COURT: Who is speaking for Janssen? Mr. Wyatt?

19 MR. WYATT: Yeah, Your Honor.

20 And I'll make this simple. We'll withdraw all the
21 company policy documents to make this easy. I think
22 previously we were okay on DHHS guidelines. I don't know if
23 we are revisiting that, but I think we had addressed --

24 THE COURT: I made a ruling on that. Didn't I? I'm
25 not revisiting that ruling. I'm talking about the additional

1 documents other than what I've already ruled on. Those
2 guidelines where you had some gap-fillers of a couple of
3 years, I've already ruled that that's coming in.

4 MR. WYATT: Okay. So the only other thing then would
5 be this Medicare prescription drug benefit manual, which I
6 thought we also previously discussed, which is Exhibit 9200 --

7 THE COURT: When you say "previously discussed," who
8 are we talking about with? Me?

9 MR. WYATT: Yeah. I thought -- maybe I'm
10 misremembering that. That was the one other example I brought
11 up besides the policy documents.

12 THE COURT: The only ones that I've moved in are
13 those policy documents where you told me there were several
14 years of policy that went in, there were some years that were
15 gapped.

16 MR. WYATT: Right.

17 THE COURT: There may be some differences, but not
18 one that you're making some substantive argument about it.
19 It's really about just covering the time period of -- the
20 relevant time period of the case, and I said those were going
21 in.

22 Outside of that, I haven't ruled on anything. So talk
23 to me about the other documents, Mr. Wyatt, but --

24 MR. WYATT: Yeah. For the sake of moving things
25 along, I'm just going to focus it down to one document. It's

1 the Medicare Part D Drug Benefit Manual --

2 THE COURT: All right. Let's hear the one document.

3 And that's not related to your June 9th letter? That's a
4 different document.

5 MR. WYATT: That's correct.

6 THE COURT: All right. So tell me what this document
7 is.

8 MR. WYATT: This is a document that sort of sets
9 forth Medicare's policies for various things, including -- and
10 I've shown it previously to the Court --

11 THE COURT: Why wasn't it admitted earlier in the
12 case?

13 MR. WYATT: I believe that a policy -- I don't know
14 if it's the same one. But this is a manual, perhaps from a
15 different year, was referenced in opening, and so we thought
16 we had an understanding that this would be admissible,
17 consistent with the broader understanding that most government
18 documents -- I understand the regulations are a different
19 deal -- but most government documents to be admissible.

20 So it's just a housekeeping issue that we never
21 formally moved it in. That's it.

22 THE COURT: I mean, it doesn't sound like
23 housekeeping, though, right? You have a strenuous objection
24 from the Relators' counsel on the case. So, I mean, it
25 doesn't sound like housekeeping.

1 What I'm asking is you have this document the entire
2 defense case. You have the document the entire case, and
3 including when you were presenting your defense. Why didn't
4 that get moved in?

5 And the reason why I ask is this issue gets brought up
6 to Relators' counsel, what, on the morning of their -- of
7 closing arguments?

8 MR. WYATT: Well, yesterday, Your Honor. We brought
9 it up yesterday.

10 THE COURT: Right. So it's on the eve of closing
11 arguments. Right? And none of these documents were provided
12 to the Court, so I have no idea what these documents are until
13 you tell me this morning, which is an hour before closing
14 arguments.

15 So how is it right that these documents will be
16 admitted, Relators could not have closed or even talked about
17 it, and I have to presume that the reason you want them
18 admitted is because you're going to speak about them in
19 closing, correct?

20 MR. WYATT: Yeah, we're down to this one last
21 document, but yes, we plan to --

22 THE COURT: Right. I mean, you wouldn't have this
23 document admitted if you weren't going to talk about it.

24 Is that fair?

25 MR. WYATT: Yes, that's fair.

1 THE COURT: So you're going to move to admit a
2 document that Relators' counsel is precluded from speaking
3 about in their closing. And all because of the untimeliness
4 of when you decided to move it in.

5 MR. WYATT: Your Honor, I actually -- I do take issue
6 with the timeliness issue because we did present this list to
7 them. They had it before we closed yesterday. They were
8 aware that we were closing subject to this list. That was not
9 lost on them.

10 They did say they needed time to consider it. It was
11 an accommodation to them that we did not move them in one by
12 one and to the jury, frankly, at sidebar, but we could have
13 done it that way.

14 THE COURT: Do you have a copy of the document that
15 we're talking about?

16 MR. WYATT: Yes.

17 THE COURT: Can I have it?

18 Patty, do you mind? He's going to come to you and
19 bring it.

20 MR. WYATT: One minute, Your Honor.

21 (Brief pause.)

22 MR. WYATT: May I approach?

23 THE COURT: You may.

24 And when was this referenced and by whom?

25 MR. WYATT: So the benefit manual was referenced in

1 opening, and it's certainly -- I mean, it's --

2 THE COURT: Yeah, I'm talking about in the trial.
3 Was this referenced in the case, though? Forget about the
4 opening statement. I'm talking about a witness or some
5 testimony that's been provided in the court.

6 Was this ever spoken about in the entire trial?

7 MR. WYATT: I don't believe that it was directly
8 spoken about. I think it's referenced in other documents, but
9 the document itself hasn't been up in connection with a
10 witness during the trial.

11 THE COURT: How many pages is this document?

12 MR. WYATT: It's a few pages. And we can -- if
13 that's a concern, we can limit it to the Section 10.6. That
14 is really what we --

15 THE COURT: I mean, look. There's a lot of concern
16 for me. And this almost relates to your letter of June 9th
17 where you have that 300-page regulation with double hearsay in
18 there and public comments and all the rest of it.

19 This seems confusing to the jury to me. I mean,
20 there's no discussion about this. There's no witness that has
21 testified about this. You haven't called anyone to discuss
22 it. And you want it to be part of the evidence that the jury
23 has in the deliberations room. I mean, I just don't
24 understand that. And if there was --

25 I've told both counsel this early on in the trial when

1 you may have had some agreements and then the agreements went
2 sour -- because this happened to Relators. They had an
3 understanding that they believed they had from Janssen that
4 certain documents were going to come in. And then when there
5 were objections, I looked at Mr. Marketos at sidebar and said,
6 "This is what agreements mean to me. Nothing." Because if
7 you have a stipulation -- unless you've entered this
8 information into the Court and it's part of the evidence, then
9 either side can change their minds, and that's the danger of
10 sitting around not moving in evidence when you think you might
11 have an agreement from the other side.

12 And now we are in the opposite boat. Right? Because I
13 precluded the admissibility of those documents based on some
14 agreement that the Relators' counsel said they had with you
15 all. And now you're telling me what? That there was some
16 agreement between you and Relators' counsel that this would be
17 admissible?

18 MR. WYATT: Well, no, we're not resting on that.
19 First, it's independently admissible. It's a document. It's
20 a government document. It's self-authenticating. It's from a
21 website --

22 THE COURT: It's not independently admissible if I
23 think it's going to be confusing to the jurors. In fact,
24 we've had no discussion about this lengthy document on Part D
25 drugs and formulary requirements. There's been no testimony

1 that you elicited from any witness you could have called to
2 talk about it. You didn't move to admit it at trial. And so
3 now I'm going to thump this at them in deliberations, and the
4 only information they're going to get about this document is
5 what Ms. Brown says about it in her closing argument.

6 MR. WYATT: Well, two things on that, Your Honor. I
7 mean, the Relators have a rebuttal, and they can address it if
8 they think it's important. It's not too late to address it.
9 They're aware of it. They've been aware of it from the
10 beginning of the case. We've cited it in numerous other
11 filings to the Court.

12 But the only thing is this morning, this document -- I
13 did recall correctly. This document came up at 8:30 -- I
14 don't have the transcript line numbers, but 8:37-ish in the
15 morning, I said, "There is one other issue I forgot about.
16 It's the CMS policy manual" --

17 THE COURT: When you say "this morning," I don't know
18 what day we're talking about.

19 MR. WYATT: Today.

20 THE COURT: Right. So you're talking about on the
21 eve of closing argument. Today was instructing the jury on
22 final instructions and closing arguments from Relators this
23 morning and Janssen in the afternoon.

24 So you're saying, well, Your Honor, at 8:30 this
25 morning, and now, you know, 30 minutes before final

1 instructions and an hour and a half before Relators' closing
2 arguments, we want to move to admit this.

3 So there is a timeliness issue to it also.

4 MR. WYATT: Sure. Let me just get to the punch line,
5 though, Your Honor.

6 After I talked about the document, the Court said,
7 "Mr. Marketos, you are aware of that exhibit specifically?"

8 Mr. Marketos: "Yeah, I am. If that's what it is, then
9 we're not going to object to it."

10 So I think that we have actually crossed this bridge.
11 That's what I recalled. The Court didn't recall it, so I was
12 prepared to argue --

13 THE COURT: Mr. Marketos, is this the document that
14 you didn't have an objection to this morning --

15 MR. MARKETOS: No.

16 THE COURT: -- that you now have an objection to?

17 MR. MARKETOS: No. I thought he was -- if you see
18 the list of documents that he's referring to, there's another
19 one relating to CMS -- you should see the information they're
20 trying to move in.

21 THE COURT: No, no. I just want you to answer my
22 question.

23 MR. MARKETOS: The answer is no, Your Honor.

24 THE COURT: All right. Well then I'm going to take
25 Mr. Marketos at his word that although he was not objecting to

1 a particular document, he didn't believe this to be the
2 document. I don't see any reason not to believe counsel's
3 representation.

4 MR. WYATT: That's fine. So just for the record,
5 Your Honor, if I can continue the description I gave of the
6 document so that the record is clear on this.

7 I said, "It's the CMS policy manual for Medicare Part D
8 that was used in opening. That was not objected to in
9 opening. I believe it's distinct from the regulation issue
10 because it's really a policy manual. It's not a
11 government" -- "it's on a government website and available for
12 all to see. So that should be admissible as well. And there
13 was an agreement at one time that there would be no objection
14 to government documents because they are admissible under
15 8038."

16 I think it's a fairly specific description of the
17 exhibit, but if that's not what Mr. Marketos claims he thought
18 I was talking about, then I have no basis to dispute that.

19 MR. MARKETOS: There was another document, D-8573,
20 called CMS Final Rule Medicare Prescription Drug Benefit,
21 Your Honor, and that is a different document and we -- they
22 represented that - this isn't called CMS anything. It's a
23 Medicare Prescription Drug Benefit manual. Okay? That's not
24 even what the document is called, and it's not how it's
25 described on this list.

1 And listen, we have a real objection because it's
2 exactly what Your Honor's talking about. They're not even
3 trying to protect the record on appeal. They're trying to get
4 documents in that didn't get in through a witness after,
5 essentially, the entire trial is over and then arguing them in
6 closing.

7 Are we going to, like, call another witness? I mean,
8 it's a real problem.

9 And look at the length of the documents and --

10 THE COURT: Yeah, I got it, Mr. Marketos. I don't
11 disagree.

12 Look, I'm not allowing this document to go in. I
13 think, one, it's been raised untimely; two, I think it's going
14 to be unbelievably confusing to the jury, which is something
15 that I have to consider. Whether a document is a government
16 document or not, there's been no testimony about this
17 document. It's being brought in at the eve of closing
18 argument. I'm not going to allow it.

19 I think that if anything, it's just going to cause
20 greater confusion to the jury on the legal instructions that
21 I've provided them already this morning. And so that document
22 is out.

23 What else do we have? Does that -- well, let me just
24 make sure. That was the only document you were focused on in
25 that batch of documents, correct?

1 MR. WYATT: That's correct, Your Honor.

2 THE COURT: So what else do have to talk about? The
3 300-page --

4 MR. WYATT: Yes, Your Honor.

5 THE COURT: All right. How is that coming in? How
6 is that not going to be confusing to the jury?

7 MR. WYATT: Well, Your Honor, we can submit -- I
8 mean, there's really only two pages that we're interested in
9 and --

10 THE COURT: Well, no. I'm asking you what you
11 submitted to move in. You wanted to move in the entire
12 document, which also has comments about things from other
13 folks, third parties?

14 MR. WYATT: Right. It's a comment in rulemaking
15 where there's a comment that CMS considers, and then it
16 responds to it. So the one comment that we did highlight is
17 then responded to in another passage that we highlighted. So
18 it's relevant to context to understand the response.

19 We are happy to address the concern about the length of
20 the document by merely submitting --

21 THE COURT: What about the hearsay?

22 MR. WYATT: Well, it's not hearsay for two reasons.
23 Number 1 is it's a government document under 8038, and also it
24 is an admission of a party opponent --

25 THE COURT: And you're saying it's a government

1 document including the third-party comments?

2 MR. WYATT: Yes, because it's context to the
3 government's response. So it's merely to understand and put
4 into context the government's response.

5 The Relators responded to this by a couple things.
6 Number 1, they argued that it's not an admission because CMS
7 is not the party, the United States is the party. But in
8 *United States v. American Telephone and Telegraph*, 498 F.Supp
9 353, District of Columbia, District Court in 1980, the exact
10 same argument was raised by the federal government. They said
11 this case is brought by the DOJ. No statements by any other
12 agency is admissible as an admission. And the court rejected
13 that saying "It makes no sense to hold that the Department of
14 Justice, which is essentially a law office, alone comprises
15 the United States." And so other documents and statements by
16 the FCC were --

17 THE COURT: Well, I didn't say anything about it not
18 being a statement of a party opponent. So why don't we get to
19 my concern, which is this document is how long?

20 MR. WYATT: The full document is several hundred
21 pages long, but we would propose --

22 THE COURT: Right. That's not going for sure.
23 Right? Because I think you can at least concede that dropping
24 a 300-plus document, whether it's a CMS document with other
25 comments, is going to be unbelievably confusing to this jury.

1 I don't know what you would expect them to do with it.

2 So are you saying now that you are revising your
3 request to only move a portion of this document?

4 MR. WYATT: Yeah. I would move in the two pages that
5 we're interested in, plus the title page. I mean, the length
6 was not an objection --

7 THE COURT: What are the two pages?

8 MR. WYATT: It's page -- let me find it, Your Honor.

9 THE COURT: And Mr. Marketos, do you have a copy of
10 this document?

11 MR. MARKETOS: We'll get one, Your Honor. It's -- it
12 is a 393-page document that has the comments in it, I think.

13 THE COURT: I don't mean that -- the whole document.
14 I mean the two pages of that document that we're about to talk
15 about.

16 MR. MARKETOS: Yeah. It's attached, as I think they
17 attached it to their letter.

18 MR. WYATT: Correct.

19 MR. MARKETOS: Yeah. I saw it attached to their
20 letter. We are -- obviously we wrote a response to it. We're
21 obviously opposed to it.

22 This is -- these are documents that if any of this was
23 relevant at all, and Your Honor permitted it to be offered to
24 the jury, interpreters of rules and regulations and CMS
25 guidelines, they would have been through the expert witnesses,

1 neither of whom -- neither side of whom called any expert on
2 Medicare or Medicaid. They didn't call theirs. We didn't
3 call ours.

4 And now it's just a last-minute attempt to get in a
5 final rule and argue that off-label is the rule to the jury.
6 That's what it is.

7 And there's no chance that the jurors should hear that
8 for the first time in closing argument. The prejudice would
9 be to us on that front. There's absolutely no chance that
10 they're going to get to argue, essentially, jury
11 nullification, with two excerpts from a CMS final rule that
12 didn't come through a witness.

13 THE COURT: What's the general gist of the two pages?
14 Without reading them verbatim so you don't torture the court
15 reporter.

16 MR. WYATT: I won't torture the Court, Your Honor. I
17 mean, there are --

18 THE COURT: No, not me. The court reporter.

19 MR. WYATT: The court reporter, I'm sorry. Or either
20 of you.

21 It's talking about -- it is recognizing that there is
22 prevalent off-label use in various areas of medicine,
23 including HIV. The purpose of using these statements is --
24 it's not to nullify anything. It goes to the issue of
25 materiality. The government recognizes the importance of

1 access to certain types of drugs, and they've argued to the
2 opposite --

3 THE COURT: Relators' counsel -- Relators' counsel --
4 well, not Relators' counsel. Relators aren't alleging,
5 though, that doctors can't prescribe drugs off-label. I mean,
6 that's not part of their case.

7 MR. WYATT: Right. But part of the statements
8 indicate that CMS believes that the rules of Part D will not
9 obstruct access to off-label medications. And so I do think
10 that's relevant to understanding how CMS itself believes that
11 the Part D framework is going to work.

12 THE COURT: With no context for it and no testimony
13 of it.

14 MR. WYATT: Well, that's --

15 THE COURT: Just whatever you guys decide it means
16 and argues.

17 MR. WYATT: Just as the jury would do with respect to
18 the 300 PILM documents that no one has ever talked about
19 either, but --

20 THE COURT: That's different. I don't know if
21 that's -- I don't consider that to be the same type of
22 document, Mr. Wyatt. I don't even know what's in there that
23 might contradict the instructions I've already provided to the
24 jury.

25 MR. WYATT: I don't think anything in here

1 contradicts it. It's consistent with the law. So the Court's
2 instructions were --

3 THE COURT: With what law? The law that I gave the
4 jury or the law that you wanted me to apply? Because it's not
5 like the instructions I gave to the jury are the same pieces
6 of law that Janssen requested me to instruct the jury.

7 So which one are we talking about?

8 MR. WYATT: I believe they are consistent. I have
9 not heard an example of anything in the pages that we're
10 talking about submitting that contradicts the law. CMS
11 implements the law. So the statute says what it says, and
12 then CMS issues regulations consistent with that.

13 THE COURT: I think this is double-edged sword.
14 Look, I will tell you, for reasons that were outlined by
15 Mr. Marketos in his submission to the Court, not necessarily
16 on party opponent statement but on the confusion to the jury,
17 I agree with Relators that this document coming in with no
18 context whatsoever, basically in advance of the defense
19 closing only, right, is when you're asking me to admit it,
20 would be unbelievably confusing to the jury and prejudice to
21 Relators.

22 I also think taking two pages out of a 300-page
23 document would have the same problems. Because now we have to
24 figure out in what context these pages have been taken out of,
25 and so I don't think it's admissible either way. And I have

1 concerns about putting that before the jury now when you've
2 had no testimony or no context during the trial regarding the
3 document.

4 And I still will put on the record, I do not understand
5 why no witnesses were called or these documents weren't dealt
6 with during -- with the Janssen's defense case. I still don't
7 understand why this was something that was waited until the
8 closing arguments, but I'm not going to allow it in.

9 MR. WYATT: Understood, Your Honor. And I just want
10 to speak to one issue about the timing of this. This was
11 raised in a letter on June 9th; our case was still open. If
12 there was a concern that this needed to be contextualized to
13 the witness, the time to raise that concern was before we
14 closed and that did not happen.

15 So I'm not able to respond to that after the fact. The
16 case did close without that objection being raised, and so now
17 I'm trying to make up for it by responding to --

18 THE COURT: Yeah, but, I mean, you want to put that
19 on the Court. That's not on the Court to figure that out. I
20 mean, you guys present your defense case in any way that you
21 want to present it. If you don't want to call a particular
22 witness, I'm not going to tell you, Hey, you guys are moving
23 to move in some evidence. I don't know how I'm going to rule
24 on this. You didn't call a witness on it. You sure you don't
25 want to call a witness?

1 I mean, I'm not here to assist either side in how you
2 present your case. But what you can't do is say, Well, Judge,
3 if we knew you were going to rule this was inadmissible, we
4 might have called a witness.

5 MR. WYATT: That's not what I meant at all, Your
6 Honor.

7 THE COURT: Well, then, I don't know. What did you
8 mean?

9 MR. WYATT: I mean that the objection was not raised
10 by the opposing party. They were aware of our intent before
11 we closed our case. They waited until --

12 THE COURT: I will tell you this, though. I have
13 concerns about the admissibility of this document for this
14 jury regardless of when the objection might have been raised.

15 I mean, we're talking about whether this would be
16 unbelievably confusing to a jury to drop this significantly
17 either lengthy document or cherry-pick two pages out of a
18 document with no context, no testimony, no discussion about
19 it, and the only discussion these folks are going to get are
20 not evidence. Because closing arguments aren't evidence.

21 And so the argument you're going to make is on this
22 document on its face with no context. And you had witnesses
23 that you could have called to bring context to this document.

24 And look, that may have been a different scenario. I'm
25 not saying that if you had called a particular witness and if

1 that witness had said A, B and C, this document would come in.
2 I can't decide that in a vacuum. But you had a better shot of
3 it doing it that way than the route you all took.

4 And look, and like I said, you all make the decisions
5 you make on both sides, but I'm not allowing this document in.

6 MR. WYATT: Understood.

7 THE COURT: You're going to have to do your closing
8 without a document that wasn't a part of this case at all. So
9 I don't even know how it impacts your closing. Everything
10 that's been presented before this jury you've been well aware,
11 and you know what you can close on. So adding this one
12 document Relators weren't able to address in their closing
13 because they might be able to fit in their 30-minute rebuttal,
14 I find that to be unfair to Relators. I'm not going to do
15 that.

16 What else on this?

17 MR. WYATT: That's it, Your Honor.

18 THE COURT: All right.

19 Let me just briefly, then, address -- Mr. Wyatt, look,
20 I appreciate the issue you raised earlier but -- with respect
21 to the closing argument, but I will tell you, folks -- and let
22 me hear from you, but there's been mudslinging in this trial
23 from both sides. And I want to be clear about this, because I
24 don't believe that what Mr. Marketos argued during closing
25 crossed any particular lines of the Rules of Professional

1 Conduct.

2 I mean, Mr. Wyatt, during this case, in the defense
3 case of Janssen, you put before this jury, whether directly or
4 implicitly, that these lawyers created this case. Right? You
5 had privileged documents -- or, I'm sorry. You had documents
6 that -- where the privilege was waived because they were
7 forwarded to third parties, and you put before this jury that
8 these lawyers that represent the Relators, they created this
9 case.

10 And that wasn't just to impugn the credibility of the
11 Relators, because that would be one thing. But the other
12 implication is that these lawyers' credibility were at stake.
13 And you guys were able to make that argument. You beat that
14 drum with multiple witnesses. You put up documents of their
15 communications with their clients basically saying, this
16 complaint, these allegations come from these counsel. Not
17 from the Relators.

18 So when I think about those issues over the break, I
19 don't think what Mr. Marketos -- his mudslinging -- you may
20 not like it, but I think, for me, it's a tit for tat. You
21 guys have been throwing some of that same mud at Relators'
22 counsel. And I don't think -- and I'm not saying they didn't
23 object to it, but you guys put that into the case.

24 And you don't agree that that, in part, impugns the
25 credibility of Relators' counsel before this jury?

1 MR. WYATT: Your Honor, I don't think it's the same
2 at all. I understand Your Honor --

3 THE COURT: Well, isn't that a violation of the Rules
4 of Professional Conduct if you're alleging that some lawyers
5 just made up facts in a complaint and are just presenting to
6 this jury it doesn't come from the actual Relators?

7 MR. WYATT: The allegation is that there is a
8 financial motivation to do this, Your Honor. That is what
9 that argument is part of. That goes to basic sort of
10 credibility and bias and motivation issues. It's not the same
11 thing as pointing the finger -- I mean, he turned to us during
12 his closing. And I don't know if he actually pointed to us,
13 but the implication was clear, and he said "counsel." And he
14 used the word "gaslighting," which is directly accusing people
15 of lying.

16 That is just completely -- in my view, and I understand
17 the Court sees it differently, that is not appropriate
18 argument.

19 THE COURT: All right. Look, I appreciate it. And
20 look, don't get me wrong. That term has maybe different
21 meaning outside of the courtroom. Maybe that's a hot-button
22 term to use. But if Mr. Marketos had said, Look, you've seen
23 the defense case. This is a lot of smoke and mirrors. Right?
24 They want you to look at a shiny object here as opposed to the
25 evidence that you should be focusing on. Would that be

1 improper argument by a counsel?

2 MR. WYATT: That is less problematic.

3 THE COURT: I know --

4 MR. WYATT: They have the definition up there on the
5 screen basically saying that we're liars. I mean, that's what
6 the definition said.

7 THE COURT: Look, I'm not saying that -- I wouldn't
8 have chosen that term, but I don't think it's beyond the pale,
9 and I don't think it's a violation of the rules of
10 professional responsibility.

11 And I understand that you think it crosses the line,
12 but I think based on some of the same insinuations that you've
13 all made, not in argument, during your defense case against
14 Relators' counsel, this has been a contentious trial. You
15 guys have put before this jury not only the issue of the
16 credibility of the witnesses, but, in part, you've attempted
17 to imply that there's some issue with the credibility of the
18 attorneys by saying this is the lawyers creating these claims,
19 not the Relators.

20 And I understand that you want to separate and
21 compartmentalize that and say, Well, let's compartmentalize
22 and say no, no. That was an attack of the credibility of the
23 Relators. That's true. I think that is what you're doing.
24 But you're also attacking the credibility of the lawyers. And
25 so when I see -- I'm not saying that you're better angels

1 should it -- you know, you might not heed to words of your
2 better angels here and maybe dial down the tone, but I don't
3 think that what was argued in closing necessarily crosses that
4 line.

5 I understand that the term is close, and I think some
6 of the phrases that I used, I think, were more acceptable, but
7 that's where I stand on it.

8 But I'm giving you both -- you know, take a breath.
9 And, Mr. Marketos, I presume that that term is not necessarily
10 going to be used in your rebuttal again?

11 MR. MARKETOS: Yeah, Your Honor. I guess, you
12 know -- we believe it describes Janssen, the company's,
13 conduct. And we specifically used it to refer to their firing
14 of Chrissy Brancaccio after -- while she was still on the
15 stand. That is exactly what we talked about. And the idea
16 that it somehow --

17 THE COURT: So, I mean, is it your position that that
18 term was being used against Janssen, the party, and not
19 Janssen attorneys?

20 MR. MARKETOS: That's how we described their conduct
21 in this case, in defending themselves in the case. If they're
22 taking it like it's the lawyers because the lawyers make the
23 argument, not one time did we get up and object, you know,
24 when they were pointing the finger, the lawyers -- you stayed
25 at the lawyers' hotel. You stayed with the lawyers; it's a

1 lawyer-driven case. Not one time did we say a word. We sat
2 here. But it's Janssen's defense of the case that we were
3 addressing.

4 THE COURT: Well, let's do this then. It sounds like
5 everybody's on the same page then. Why don't we ensure that
6 moving forward this afternoon that if you're attacking the
7 conduct, the attack is on the party and not the counsel.

8 MR. MARKETOS: Yeah, and that's true.

9 THE COURT: Is that fair?

10 And to make it clear so that neither counsel believes
11 that there's some implication that the attack is on the
12 credibility of the counsel rather than the party.

13 I mean, isn't that what you asked me to do anyway,
14 Mr. Wyatt?

15 MR. WYATT: Yes, Your Honor.

16 THE COURT: Well, then, there you go. You've both
17 been directed to make sure that if you're going to have
18 those -- whatever it is you're arguing in closing with respect
19 to whatever adjectives you're using with respect to the
20 parties, make sure that it doesn't appear that you're making
21 some insinuation about your adversary as far as counsel.

22 Fair enough?

23 MR. MARKETOS: For sure, Your Honor.

24 THE COURT: All right. Mr. Wyatt?

25 MR. WYATT: Yes, Your Honor.

1 THE COURT: All right. Well, then, that's where we
2 are on that.

3 MR. MARKETOS: Thank you, Your Honor. I just want
4 to -- this is important to me.

5 Not one time during the course of this case have we
6 taken a shot at opposing counsel, and I hope the Court
7 recognizes. Not one time. And that's important to me, and I
8 hope that the Court recognizes that. Not one time have we
9 taken a shot. It's important for me and the reputation of my
10 firm.

11 THE COURT: All right. I appreciate that.

12 And Mr. Wyatt, you've heard from Mr. Marketos. And to
13 the extent you heard it differently, at least -- he's at least
14 expressing on the record what his intentions were and what his
15 intentions will be in his rebuttal argument. He'll ensure
16 that any credibility attacks are focused on your client and
17 there's not some implication that it might be about counsel.
18 And I think that's what you asked me to talk about and that's
19 what we've addressed. And I presume the same will go for
20 Ms. Brown in her closing argument.

21 MR. WYATT: Understood, Your Honor. And I hear
22 Mr. Marketos, and my recollection is different, and the record
23 will show what it is. But I accept the intent -- the
24 explanation of the intent.

25 THE COURT: All right.

1 What else do we need address then, folks, before we get
2 to Janssen's closing, other than I'm going to give you a few
3 minutes to -- a brief recess?

4 MR. MARKETOS: Nothing from us. Thank you,
5 Your Honor.

6 THE COURT: Mr. Wyatt?

7 MR. WYATT: Yeah, nothing from us, Your Honor. We
8 appreciate the -- just a short break to --

9 THE COURT: Absolutely. Look, we're going to take
10 ten minutes. I'll let the jurors know. They're
11 probably finishing up there.

12 And then, Ms. Brown, are you going to be ready in ten
13 minutes to proceed with your closing argument?

14 MS. BROWN: Yes, absolutely.

15 THE COURT: And do you have a sense of how long it
16 is?

17 MS. BROWN: Probably -- no more than two hours. I
18 hope a little shorter.

19 THE COURT: All right. It may be less, but you're
20 going to keep to my two-hour mark.

21 MS. BROWN: Yes.

22 THE COURT: All right. Fair enough. We're in
23 recess, folks. You can remain seated.

24 (A short recess occurred.)

25 THE DEPUTY COURT CLERK: Remain seated. Court's now

1 in session.

2 THE COURT: All right, folks. Anything we need to
3 talk about before we get the jurors?

4 MR. MARKETOS: No, Your Honor.

5 THE COURT: All right. And just a reminder, we'll
6 take a ten-minute recess after closing before your rebuttal,
7 Mr. Marketos, so you'll have a break there. Okay?

8 MR. MARKETOS: Thank you, Your Honor.

9 THE COURT: All right.

10 THE DEPUTY COURT CLERK: All rise.

11 (The jury enters the courtroom.)

12 THE COURT: Folks, everybody be seated.

13 All right, folks, we're going to continue with closing
14 arguments.

15 Ms. Brown, are you ready at this time to proceed with
16 Janssen's closing argument?

17 MS. BROWN: I am. Thank you very much, Your Honor.

18 THE COURT: All right.

19 MS. BROWN: Good afternoon, everyone. I hope lunch
20 and the cannolis were terrific. Well, I hope it was good what
21 you did have.

22 I want to start by thanking you all very, very much for
23 your jury service here. This has been a long trial and you
24 have been a terrific jury. You have shown up on time every
25 day. We have literally never had to wait for you, and I know

1 you have had to wait for us a bunch. But you have been
2 timely, you have been patient while we handled things at
3 sidebars, while I ask questions again and again and again, and
4 you were patient and attentive. And so from me, from
5 Mr. Wyatt, from Mr. Klein, but most importantly from the folks
6 at Janssen, thank you very much for your jury service in this
7 case. It has allowed us to defend ourselves against
8 allegations and accusations that we do not believe the
9 evidence has supported.

10 So we're at the end. We made it. And you have seen
11 everything they have to prove to you that they've met their
12 burden. Relators, and Relators alone, have the burden of
13 proving to you that we defrauded the government, we knowingly
14 defrauded the government into paying for HIV medicines
15 prescribed for HIV patients to treat HIV.

16 They haven't come close to meeting that burden or to
17 meeting the burden of proving to you that we paid kickbacks to
18 doctors like Ricky Hsu who came in here and told you that he
19 finds the allegations in this lawsuit to be extraordinarily
20 offensive. He said, "We are not in this because we're being
21 paid by a company. We choose to do -- we choose the right
22 drug for the right person because it's best for them. It's
23 offensive, it's ridiculous, and you should know that
24 yourself."

25 That's what Ricky Hsu had to say about the claims that

1 are being made in this lawsuit.

2 Relators have not come close, at the end of almost six
3 weeks, Relators have not come close to meeting the burden of
4 proving to you that it is more likely than not that we
5 knowingly defrauded the government and willfully paid
6 kickbacks to doctors. Here's what would have to be true for
7 the Relators to come close to meeting their burden.

8 First, we would have to have engaged in a nationwide,
9 coast to coast, California to New Jersey, a nationwide
10 conspiracy to promote off-label and bribe doctors during the
11 time period that we were part of a corporate integrity
12 agreement, when the government was literally monitoring and
13 checking and reviewing and meeting with us, looking at all of
14 our promotional materials and all of our speaker materials.
15 That would have to be true for them to have made their burden
16 here.

17 What would have to be true is that claims for Prezista
18 and Intelence to treat HIV patients were false, even though
19 they were prescribed for HIV patients, and they were indicated
20 to treat HIV.

21 What would have to be true is that our conduct caused
22 doctors to prescribe Prezista and Intelence improperly, even
23 though they didn't bring you a single doctor, not a single
24 doctor to say that that's true.

25 What would have to be true is that we would have had to

1 have caused the Plan D sponsor to submit false claims to
2 Medicare, even though there wasn't a single Plan D sponsor who
3 testified in this case, and there isn't a shred of evidence in
4 this case about what the Plan D sponsors evaluated when
5 determining and certifying that a claim is reimbursable by
6 Medicaid.

7 What would have to be true for plaintiffs to meet their
8 burden here is that the government would not have paid for
9 Prezista and Intelence, even though we have a national
10 strategy to make these medicines easily accessible to everyone
11 who needs them, and not a single CMS witness came in here to
12 say CMS would not have paid.

13 This is a case where plaintiffs allege a remarkable
14 700,000 contacts with -- by Janssen employees and physicians.
15 You heard Dr. Shaked, 5,177 doctors contacted over the course
16 of eight years, and nearly one million claims submitted to
17 Medicare. That's a lot of data. That's a lot of contact over
18 a long period of time.

19 And yet, to meet their burden, they brought you no one.
20 They brought you not a single doctor to support the
21 allegations that they're making in the case. They didn't
22 bring you a single representative of a Plan D sponsor. We
23 don't even know who they are. We don't know how many there
24 are. We don't know who they are. We don't know how they
25 decided to send claims for reimbursement to CMS because they

1 didn't bring that evidence in the case.

2 And they are the only party that has that burden. We
3 got sued. They carry the burden of proving to you that what
4 they claim in this lawsuit is the truth and is supported by
5 the evidence.

6 They didn't bring a single CMS employee.

7 And we heard a lot this morning about patients. They
8 didn't bring a single patient to support their claims. They
9 are alleging a nationwide conspiracy for almost a decade,
10 affecting 5,100 doctors, 700,000 times, and not one person
11 came in here to say that that was true. Not a doctor, not a
12 Plan D sponsor, not CMS, and not a patient.

13 Almost all of the testimony that we heard in this case
14 was on the left side of the chart. Almost every piece of
15 document and witness testimony that came in was from a sales
16 rep or a former sales rep or a hired expert witness. We heard
17 nothing from anyone at the pharmacies. We heard nothing about
18 the Plan D sponsors, and we certainly heard no one from CMS.

19 And this is how, undisputed in the case, a claim gets
20 to the government. It's got to be written by a doctor, sent
21 to a pharmacy, sent to a Plan D sponsor who makes a
22 determination about whether or not it's reimbursable, and then
23 sent to CMS. And all of the testimony was on the left side of
24 the graph. They didn't bring you any information on the
25 right. And that's not a defense tactic. That's not an

1 argument. That's the truth of the evidence in this case.

2 What the evidence in this case has shown, folks, is
3 that this lawsuit is not about helping the government. CMS to
4 this day continues to pay for these medicines. From the
5 moment these medicines were approved until today, CMS
6 continues to reimburse. And what you're going to hear about
7 it and what you heard in this trial is there a number of
8 actions the government can take if it is concerned about the
9 types of things that they're alleging in this case.

10 And no evidence came from CMS that they audited us,
11 that they put utilization programs in place, that they stopped
12 payment for these medicines. Nobody came to testify to you
13 that CMS would not continue to pay for these drugs as they
14 have done.

15 And one of the things that's critical, when you look at
16 the elements and the jury instructions and you're trying to
17 evaluate the claims that they're making in this case, is the
18 role of the government in babysitting us during the time
19 period in this case.

20 During the time period in this case, we were part of
21 Corporate Integrity Agreements, and you have heard a ton about
22 them. And those Corporate Integrity Agreements gave the
23 government and an independent third-party organization
24 tremendous oversight and tremendous monitoring power. These
25 Corporate Integrity Agreements were set up and required a

1 third party to audit us, to look at our books, to look through
2 all of our documents, to provide annual reports, to meet with
3 employees, to look at the very, very documents and issues that
4 they're complaining about in this lawsuit. Speaker programs.
5 They looked at speaker decks. They looked at the requirements
6 to be on a speaker bureau. They set a number of how many
7 speaker programs we had to observe and audit. They looked at
8 our training documents. They looked at all of our policy
9 regarding speaker bureaus. Everything that went up on the
10 screen this morning that they're complaining about, the
11 independent third-party organization put in place by the
12 United States government looked at during this time period.

13 You might remember Dr. Amit Patel told you he was
14 interviewed by the government as part of one of the Corporate
15 Integrity Agreements, because they have the power to show up
16 whenever they want and meet with whoever they want and request
17 whatever documents they want. And they did, and Dr. Patel
18 told us about that.

19 He also told us about a product-specific risk
20 mitigation plan that the government required us to put in
21 place for these medicines. Dr. Patel talked about it. As
22 part of this corporate integrity agreement, we needed specific
23 plans about compliance on these medicines that the government
24 looked at and reviewed and had the ability to audit. They
25 also looked at promotional pieces, and we'll talk about the

1 lipid claims and proven lipid profile. Government had
2 unfettered access to all of that stuff as well. And you
3 heard, when doctor -- Ms. Evans was here, the government had
4 significant power to punish us if we were not doing what was
5 required of us under those Corporate Integrity Agreements.
6 They had the power to issue daily fines. Every day, if they
7 had found us not to be in compliance, we could have been fined
8 every single day, a number of different statutory fines. They
9 had the power, when they were babysitting us and checking up
10 on us, they had the power to kick us out of Medicaid and
11 Medicare and any federal health care program. If when they
12 came in and looked at all the documents that these folks are
13 complaining about in this lawsuit, if when they came in, they
14 looked at those documents and had concerns, they could have
15 said, Janssen, you can't participate in Medicare. You can't
16 participate in any federal program. They had serious powers
17 to punish us if we weren't complying. They could have pursued
18 enforcement action as well.

19 And what the evidence is is that none of that happened
20 because Janssen met its requirements under these Corporate
21 Integrity Agreements. But what's critical about these
22 agreements -- and we have heard so much about them in the
23 trial, other medicines, other drugs -- but they're important
24 because what came with those settlements, what came with those
25 agreements was incredible oversight by the government. And

1 what the Relators in this case are alleging is essentially
2 that they discovered a nationwide conspiracy that our United
3 States Government missed, that even though the United States
4 Government was checking on us and monitoring us as part of a
5 written agreement, the Relators, through their own work,
6 discovered a nationwide conspiracy.

7 And you heard about the ways in which the Relators went
8 about getting evidence as part of their lawsuit. You heard
9 about reaching out to third parties and pretending to need
10 data that they were only collecting for a lawsuit. You heard
11 about accessing colleagues' accounts so that they could get
12 data that had been requested by their lawyers for part of the
13 lawsuit. You heard and you saw with Ms. Brancaccio and
14 Ms. Penelow the documents that they took from Janssen and
15 emailed to their personal accounts, and you saw and you heard
16 about secret recordings of colleagues and doctors that they
17 made for their lawsuit.

18 What the evidence has shown in this case is that this
19 is not about helping the United States Government at all.
20 It's about helping Ms. Brancaccio and Ms. Penelow, who stand
21 to gain an enormous amount of money from a recovery in this
22 case. And what was perhaps most shocking on that score is
23 when we learned that they've already split up money they don't
24 even know they're entitled to. But they've already had
25 multiple discussions about how they're going to split up money

1 that they've come to ask you all for. This is not about
2 helping the government. This is not a case about taxpayers.

3 Relators' and their friends' testimony to you all under
4 oath has not been credible, has not been truthful, and has not
5 been accurate. These folks are the folks that came to
6 testify, and they are all connected in some kind of a way.
7 Ms. Penelow and Ms. Brancaccio are the Relators, of course.
8 Ms. Penelow is friends with Ms. Graham, who works with
9 Ms. Strand and is married to Mr. Wilhelm. Mr. Wilhelm and
10 Mr. Grooms are friends, and Mr. Grooms and Ms. Strand worked
11 together for a period of time. And Mr. Holshoe and
12 Ms. Penelow are friends. These are not perfect strangers.
13 These are folks who have a connection, who worked together
14 and, in many different ways, are connected.

15 At the start of this lawsuit, the Relators told you
16 that this case is going to be about the credibility of the
17 witnesses. They said, You get to ask, are what these
18 witnesses saying, is it consistent with one another and do
19 they remember the types of details that you would expect to
20 hear from someone who was telling the truth?

21 Ms. Penelow agreed. The truth doesn't change. If
22 something happened, it happened, and if it didn't, it didn't.
23 But when they came in here to testify to you, the truth
24 changed a lot of times. And you were instructed by the judge
25 today that part of your job as jurors is to evaluate that

1 credibility. Part of what your jury instructions say -- and
2 you'll have them back with you in the jury room -- is that you
3 are the judges of the credibility and you are to consider the
4 very things like Did this witness say something different
5 outside of this courtroom? Has the witness changed his or her
6 testimony? And does the witness have a financial bias that
7 might impact their testimony?

8 So let's talk a little bit about some of the topics
9 that led to testimony that changed right in front of you all.
10 Everyone who came in to testify agreed that they had a
11 responsibility under J&J policy, under Janssen training to
12 report any potential noncompliance. Everyone knew how to do
13 it, and everyone knew they had a responsibility to do it.
14 There was a hotline. There was a compliance department.
15 There was HR. There were supervisors. There were iPad apps
16 where they could report it, and everyone told you they didn't
17 do that, they did not raise these concerns when they were
18 working at Janssen.

19 And many of them continued to work, and they claim they
20 continued to promote off-label for many, many years.
21 Ms. Brancaccio says she did that even after she got a lawyer,
22 even after she filed a lawsuit.

23 And that was a problem for their case, that outside of
24 the lawsuit, nobody ever raised their hand and said, Hey,
25 something's not right. And so the testimony that came in in

1 this courtroom to you all changed multiple times with multiple
2 witnesses. You heard that Ms. Penelow was asked about whether
3 she had ever reported this activity under oath in something
4 called an interrogatory back in 2008. And she swore under
5 oath that the truth was that, in 2012, she had met with
6 Ms. Megan McGrath in Janssen's human resources department and
7 complained regarding pressure to market Prezista and Intelence
8 off-label. This is in 2018, October of 2018.

9 A few months later, in January of 2019, she was
10 deposed. You guys have heard a ton about depositions, sworn
11 testimony under oath. She said it again. She said during
12 that time period, November of 2012, "I decided to go to human
13 resources and report its off-label activity." She was asked
14 in multiple spots of the deposition, and she said, "I reported
15 it to human resources, and I have a tape. I taped the
16 conversation."

17 And so we asked, "Can we have the tape? Send us the
18 tape." When we got the tape -- and you got to listen to some
19 of that during this trial -- it said no such thing. What she
20 had said in the sworn statement and in her deposition about
21 reporting to HR, it wasn't on the tape that she said it was,
22 so she had to change her testimony. So she deleted testimony
23 that she had reported this to human resources. And these are
24 the types of details that you would expect somebody who is
25 telling the truth to remember. "Did you report a nationwide

1 conspiracy to promote off-label?" That is a detail that you
2 would remember.

3 Ms. Penelow corrected and said, "Actually, I didn't
4 report it. I didn't -- I don't have that recorded."

5 And then she came into this court and told you all
6 something different. She was asked in this court to confirm
7 that, actually, her testimony under oath had been wrong. She
8 had never reported it on the tape that she produced to us, and
9 she agreed.

10 "One thing you absolutely did not do in this meeting
11 was raise any concerns that there was off-label promotion.

12 "That's correct."

13 But then she told you something that also wasn't
14 correct, that also wasn't accurate. She was asked, "So
15 earlier in 2012 or maybe 2011, you called Ms. McGrath to
16 explain what was happening with Tony Dolisi and the off-label
17 marketing."

18 She said, "Yes, I did. I told her everything."

19 We had to bring you Ms. McGrath. We had to bring you,
20 for a very, very short period of time, Ms. McGrath, who told
21 you it was physically impossible for that testimony to be true
22 because she wasn't even working at the company at that time
23 period.

24 "Is it physically impossible that any conversation
25 between you and Ms. Penelow took place?

1 "Correct, because I wasn't even working there."

2 And Ms. McGrath confirmed for you that she had never
3 had a conversation with Ms. Penelow. You will have to judge
4 that credibility. Is reporting a nationwide conspiracy to HR
5 a fact that you would expect someone to remember?

6 Ms. Penelow also had changing testimony, even before
7 you, all about whether she did or did not promote off-label
8 and how much or how little she did. She started saying she
9 had refused to promote off-label and then changed various
10 pieces of time to say she wasn't sure, maybe not 2007, maybe
11 50 percent, maybe 70 percent. The testimony even here in this
12 trial was not consistent and certainly was not consistent with
13 prior testimony.

14 Then we heard from Ms. Strand early on in the trial,
15 and she had similar stories about reporting. She started her
16 testimony when we reminded her that we had asked her before,
17 "Have you ever reported this before?"

18 And she said, "No. I have never reported this. I
19 never told anyone. I never reported anything outside of this
20 lawsuit."

21 But when she came in here to testify in front of you
22 really, really early on in the trial, she had a different
23 story. She said, "Now I realize that, actually, I called the
24 FDA. I didn't realize that until I went back and I looked at
25 my email trail." That's what she told you when she was here

1 for the first time, inconsistent with her deposition. And we
2 said, "Hold on. You realized that looking at your emails?"

3 And she said, "Yes. When I started to look at some
4 emails from Tibotec, I remembered I called the FDA."

5 So we said, "Well, where did you find the email? Like,
6 when did this email get discovered?"

7 She said, "Well, actually, it wasn't necessarily an
8 email. I was just looking at emails from Tibotec."

9 And we said, "So you had forgotten that you had gone to
10 a federal agency to report this?"

11 And she said, "Yes." It had actually just slipped her
12 mind.

13 And we said, "Well, when, for the first time, did you
14 realize that you had called a government agency?"

15 She said, "Probably sometime in the last six years."

16 And then we said, "Well, about the emails? Tell us
17 what the emails were."

18 And then she said, "No. I actually wasn't looking at
19 anything at all. It actually wasn't an email. It just sort
20 of popped into my head."

21 Wasn't even an email even having anything to do with
22 Tibotec.

23 In the end what Ms. Strand testified is she actually
24 didn't speak to anybody at the FDA. At the end of all of this
25 story -- and you might remember the testimony -- it sounded

1 like she called. She said she left a message and nobody
2 called her back. You'll have to sort through this. Her
3 testimony outside of the courtroom is she never reported
4 anything, and then we got a very long, complicated story about
5 maybe calling the FDA when maybe she looked at some emails
6 when she came in here.

7 Another thing the Relators' counsel told you in their
8 opening statement is that when you are judging credibility,
9 you will judge whether what the witnesses are saying are
10 consistent with one another. Is what they came in here to
11 tell you consistent?

12 And before they all came in, before trial, you heard
13 that lawyers had written up declarations for them. Lawyers
14 representing Ms. Penelow and Ms. Brancaccio had typed up
15 statements, and they all signed them and they were consistent.
16 The statements that were written outside of this courtroom
17 were consistent, and, in fact, as we showed you, in some
18 instances they were the same. They were copied and pasted
19 from one declaration to another.

20 And you heard about Ms. Brancaccio reaching out to some
21 of the friends on the chart to say, Hey, could you please sign
22 these declarations? They're helpful to my case.

23 But what happened when those witnesses came in here is
24 that details about these allegations that you would expect to
25 be consistent if they were the truth, they were inconsistent.

1 For example, Ms. Penelow -- Ms. Brancaccio testified that
2 everybody was instructed to promote Prezista for
3 treatment-naive. Nationwide scheme to promote Prezista for
4 treatment-naive. But when Mr. Grooms came in here, he said he
5 couldn't really recall that ever happening. He's not familiar
6 with that part of the nationwide conspiracy.

7 When Mr. Wilhelm was in here, he said every day, on a
8 daily basis, the sales force was promoting Intelence for
9 treatment-naive. Every day they were all instructed, every
10 day in the field, Intelence for treatment-naive.

11 But when his wife, Donna Graham, came in here, she said
12 she never heard of that. Intelence for treatment naive, I
13 don't remember that. It could have happened after I left, but
14 I'm not sure.

15 And Ms. Brancaccio, if you remember her videotaped
16 deposition, she didn't remember that one either. She didn't
17 remember this part of the conspiracy until they took a break
18 and she met with the lawyers and she was reminded.

19 (Video clip played at this time.)

20 MS. BROWN: Same thing happened with lipid friendly.
21 You heard from Ms. Brancaccio that everybody was instructed to
22 use the term "lipid friendly." But when Mr. Holshoe came in
23 here, he said he never remembers that. He never remembers
24 using the term "lipid friendly."

25 They have alleged a nationwide conspiracy where

1 everybody was given the same instructions to do the same
2 things, and their testimony, when they came before you, was
3 not consistent at all.

4 You saw this email that Ms. Brancaccio sent to
5 Ms. Penelow, I believe, and her lawyers, talking about finding
6 documents at Janssen and how she thought the documents she had
7 found would be a home run in her lawsuit. And these documents
8 talked about something called binding affinity, which isn't
9 even a claim in this lawsuit. She's sending emails about a
10 totally different claim that's not even at issue here.

11 And we said, "You believed there was a problem with
12 binding affinity? That's a type of promotional message?" And
13 that's no longer a problem she was raising in this lawsuit.

14 They're alleging a nationwide conspiracy, but the
15 claims of what they claim were at issue were not consistent
16 when the witnesses came in to talk to you.

17 The same happened with allegations about Ray Pecini.
18 You guys might remember this. He's the medical science
19 liaison. So when doctors have questions that sales reps
20 couldn't answer, Mr. Pecini would be able to go in and talk
21 about things because he has a medical background.

22 But Ms. Brancaccio made the allegation that nobody
23 wanted to send Mr. Pecini in because he was too ethical. And
24 she accused Nancy Bartnett of saying, "If somebody needs
25 medical advice, don't send Mr. Pecini. Make sure Nancy

1 Bartnett goes in."

2 And then you all remember there was a secret recording
3 regarding Nancy Bartnett. Ms. Brancaccio had taken in her
4 purse her cell phone and taped Ms. Bartnett. And the only
5 secret recording we have of Ms. Bartnett, she was inviting
6 Mr. Pecini.

7 (Audio clip played at this time.)

8 MS. BROWN: The allegation is that Ms. Bartnett was
9 instructing sales reps not to allow Mr. Pecini to go meet with
10 doctors. And the only tape we have of Ms. Bartnett shows just
11 the opposite. Shows Ms. Bartnett inviting Mr. Pecini in to
12 meet with Dr. Turett.

13 And you heard from Tim McSherry, who came in here from
14 the very same district as Ms. Penelow and Ms. Brancaccio and
15 told you the idea that people wouldn't allow Ray to meet with
16 doctors doesn't even make any sense. The idea that we would
17 send Nancy Bartnett to meet with doctors she didn't know
18 doesn't make any sense, because Ray Pecini knew these doctors,
19 had relationship with these doctors, and if he wasn't going in
20 to meet with the doctors, the doctors would know something was
21 wrong.

22 These facts, these critical facts have not been
23 consistent as the evidence has come to you from the group of
24 friends who testified.

25 The Relators have misrepresented documents to support

1 their lawsuit, and it happened again this morning. Repeatedly
2 documents have gone up on the screen in this trial where the
3 top is blacked out, where the bottom is blacked out, where
4 it's only zoomed in to a little part of it, and the context is
5 missing and the documents are being misrepresented for
6 purposes of the lawsuit, and it happened again this morning.

7 This document went back up on the screen during
8 counsel's closing statement. So Dr. Sillup was here. You
9 might remember he was their marketing expert, and he said at
10 trial -- and he used this slide on the right-hand side and
11 said, "Wow, this is a bold off-label marketing strategy"
12 because this is a document that talks about using MIRs to get
13 48-week data into the hands of all customers.

14 And he said, "Oh, my word. I've never seen anything
15 like this. This is a bold strategy to promote off-label."

16 That's what he told you all from this witness stand.

17 But what he had said under oath at his deposition, just
18 a few years ago, was just the opposite, because he looked at
19 the full document in his deposition, not just the little part
20 that counsel pulled out on the screen. He looked at the full
21 document. And what the full document says is the reason
22 doctors were asking for MIRs. The full document contains the
23 context at the top. Many questions have come up around the
24 durability of 48-week data that was presented at a conference
25 in Toronto. The reason 48 MIRs were being used to get data

1 into the hands of doctors is because doctors were asking for
2 it when they went to the conference.

3 And when Dr. Sillup was deposed, rather than tell you
4 all that this was a bold off-label strategy, he said this was
5 an appropriate use of an MIR.

6 But it happened again today that they pulled out just
7 that bottom part of this document and tried to suggest to you
8 all that it meant something that we know it doesn't and that
9 their own expert agreed it doesn't. And that's not right and
10 that's not fair. And in standing up and defending this
11 document to you all and defending this company, we are not
12 playing lawyer tricks. We are showing the truth, and we are
13 getting all of the information in front of you all.

14 This is another email where Dr. Sillup did the very
15 same thing. And you all might remember this email because
16 it's gone up multiple times in the trial. It is an email from
17 Frank Murphy about MIRs. And Mr. Sillup, when he was in here,
18 said, "Oh, my goodness, this is an effort to solicit MIRs."

19 But that's also not fair. The document says just the
20 opposite. The document is about a use of resources. You all
21 can kind of see that up top. And it talks about using the MIR
22 resource to answer unsolicited questions, not solicited, not
23 questions we're trying to ask the doctor to get us.
24 Unsolicited questions.

25 And it goes on to say, "We want all of your commitments

1 to use this resource when asked by your customers. When the
2 doctors ask you, we want you to use this resource." But we
3 have been here for six weeks, and you guys know how many times
4 this Frank Murphy MIR email went up with the suggestion that
5 it was an instruction to solicit MIRs. The words of the
6 document say "unsolicited." That is not right and it is not
7 fair.

8 And what we know about the MIR process is that doctors
9 have to sign and certify that the request was unsolicited.
10 Look right down here at the bottom. This is a medical
11 information request, an MIR. And before we respond and send a
12 doctor information, they have to sign for it. And it says,
13 "By signing, I certify that this is based solely on my
14 unsolicited request for information and that I was not
15 prompted to complete this form."

16 And Tim McSherry was here, and he told you how absurd
17 the suggestion is that sales reps were just sending out MIRs
18 by forging doctors' signatures. He said, "If I just play it
19 out in my mind, so if I forge a doctor's signature, then the
20 doctor gets, like, a giant package in the mail saying he
21 requested information that he didn't request, wouldn't he call
22 the company?"

23 These MIR responses were big. They included the
24 package insert. They included scientific studies. They
25 included a letter, a summary. The allegation that people were

1 just forging signatures and getting stuff sent to doctors with
2 no doctor complaining, it doesn't even make sense.

3 This is another document that Dr. Sillup used to say we
4 were -- we had a strategy to promote off-label. And you all
5 might remember these graphs talking about market share and the
6 addressable market. And it went up again this morning with
7 the suggestion that this showed that our forecast included
8 off-label sales. And the document itself shows it does not.

9 And when Debbie Kenworthy was here, the business
10 analytics specialist, she explained what the document shows.
11 She explained that if you look at the left side of the
12 document, you see that in fiscal year 2007, in that maroon bar
13 graph, we're forecasting 17,000 new patients.

14 And if you go over to the addressable market, you see
15 that those 17,000 patients are well within the conservative
16 part of the addressable market. But this slide was put up
17 with multiple witnesses and misrepresented to you all as
18 suggesting we had forecasted off-label sales. The document
19 shows by simple math that's not true.

20 And it happened with this segmentation chart again and
21 again and again. This chart went up with multiple witnesses
22 who said, Look, anything other than segment H at the right
23 side of this chart is off-label. So if they need more than
24 19,000 patients, they have to go into off-label. And it
25 happened a lot in the beginning of the trial.

1 And it wasn't until Ms. Kenworthy came here and showed
2 us how you read this chart that it finally became clear that
3 that testimony wasn't right and it wasn't accurate. She
4 explained that the way you read the chart is from left to
5 right, and that as you move from left to right, you have to
6 drop the patient into the bucket where the patient fits. And
7 what that could mean is that you drop a patient in
8 simplification or you drop a patient in side effects because
9 that's the reason that they're switching.

10 And it doesn't mean that those segments are off-label.
11 And that's the correct and accurate testimony about this
12 chart, but multiple people used this chart to try and suggest
13 to you something that is not right and is not true.

14 Happened with this chart, too. Dr. Sillup told you
15 this was evidence of Janssen analyzing speakers, doing an
16 analysis on the profitability of speakers or analyzing speaker
17 programs. But what he cut out of his graph is the asterisk at
18 the bottom that shows we removed speakers from this analysis.
19 That is a misrepresentation of this document. Doctors with
20 more than one attendance have been removed as they are most
21 likely the speakers.

22 Here's another one that Dr. Sillup used. This is one
23 of those market surveys that you all heard about, where we
24 would call up doctors and ask, What messages are familiar to
25 you? What's on your mind? What's important to you? And

1 these doctors gave the comment that QD, or once-daily dosing,
2 was getting a lot of attention. This made it into our
3 marketing survey.

4 And Dr. Sillup came in here and said, based on that
5 comment, he knows that our off-label marketing message was
6 working. But that wasn't true. And Ms. Kenworthy came in
7 here and explained to you that you have to look at the
8 underlying data in these surveys to understand what a comment
9 like QD dosing was important means.

10 And when you look at it, you see what happened in a
11 situation like this. "Did you ask any specific questions
12 about the company, about the product?"

13 And the doctor here said, "Yes. Why won't the company
14 go after once-daily dosing now that it's only two tablets?"

15 Well, "Was the representative" -- we're in the middle
16 column. "Was the representative able to address your
17 questions?"

18 "Nope. Because it's not in the package insert.

19 "Well, how did you view the conversation?

20 "It was positive. My reps are knowledgeable about
21 Intelence and Prezista, but they're not allowed to give me
22 advice on using it once daily or in a naive patient."

23 That's what the underlying data of these surveys tells
24 you, what the actual information that was coming from the
25 doctors. And Ms. Kenworthy talked to you all about this large

1 set of data she has access to from these surveys. She told
2 you she has looked at and reviewed surveys of thousands of
3 doctors across the country, totally candid answers to
4 questions. What are people telling you? What's on your mind?
5 What did the sales rep say to you? She's looked at that data
6 nationwide, hundreds of sales reps. She believes she looked
7 at a representative sample, and she didn't see any red flag
8 that there was this nationwide conspiracy that's been alleged
9 in this lawsuit. She is looking at the data. If this was
10 really happening, if sales reps from here to California were
11 going in, Intelence naive, Prezista naive, lipid problems,
12 talking about QD dosing, it would have been picked up in Deb
13 Kenworthy's data, and it wasn't, because it wasn't happening.

14 Ms. Kenworthy talked about this email. You remember
15 seeing this quite a lot in the beginning of the trial. It is
16 an email from Ben Kozub, who was a marketing individual, and
17 this section down here at the bottom, "What are the off-label
18 opportunities for NNRTIs, including Intelence," was called out
19 a lot with a lot of witnesses, and it was suggested to you all
20 to be evidence of off-label promotion.

21 But when they did that, when they put this document up
22 on the screen, when they suggested with witnesses that it's
23 evidence of us promoting off-label, they knew there was a
24 response, and Deb Kenworthy told you about it. They knew this
25 document existed. "Clearly, we can't make any recommendations

1 or support for off-label promotion for any of our products."
2 And Deb Kenworthy was on the email, and she testified that was
3 her recollection, too. That was her understanding, too.
4 Because if there's one thing that we've seen so much in this
5 trial is taking things out of context in an email is not right
6 and it's not fair, and it doesn't give you the complete
7 picture of what people were really doing and really talking
8 about at that time. Someone responded right away and said,
9 "Of course you don't mean that we're going to promote
10 off-label."

11 Then we got to the Joanne Cesario documents. Let's
12 talk about what happened there. There were documents that
13 were produced in the middle of this trial, and I can only
14 close on evidence that is in the record, so I can only talk to
15 you about the documents and the evidence. I can't give you
16 any more information about that except to talk to you about
17 what the documents say and question why you were not shown the
18 complete evidence in these documents. Here's what happened.

19 Ms. Kaucher came back to finish her testimony once we
20 got the documents. And she was questioned about why she
21 didn't have any notes. Where are your notes? But what about
22 the notes? Shouldn't you have notes? You did the interview.
23 Where are the notes? They had the notes. They had multiple
24 pages of notes. These are the notes. They're detailed notes
25 of interviews with multiple people as part of a robust

1 investigation to make sure that there wasn't any off-label
2 promotion going on. Those -- nobody asked Ms. Kaucher about
3 that. Where are the notes? They know because they had them.
4 And here's what happened in the investigation. She was
5 asked -- first of all, this was a joint investigation between
6 HR and compliance. There were HR issues that were raised
7 about compensation and other issues that weren't called out of
8 this document. Both parties were part of the investigation,
9 and Ms. Kaucher had a role. She had a role supporting the
10 executives doing the HCC investigation, and this, number 2,
11 was the area that she looked into and that she testified to
12 you all about. Allegations of off-label promotion. I'm sorry
13 it's kind of small for you guys over there. I hope you can
14 see it. Let me read it. Allegation Number 2 was that "Murphy
15 has engaged in off-label discussions with several physicians
16 while on sales calls with Cesario. Findings, unsubstantiated.
17 Grimes spoke with several of the physicians to whom Murphy
18 allegedly spoke off-label. All of the physicians denied that
19 Murphy participated in off-label discussions and, further, all
20 the sales reps interviewed, except Cesario, stated that they
21 had never heard Murphy engage in any off-label discussions."

22 And these notes that weren't put in front of
23 Ms. Kaucher, that weren't put in front of you during this
24 trial, show in-depth interviews with these sales
25 representatives. Not a perfunctory, a whitewash investigation

1 where somebody just checks the box. This interview reports
2 asking this representative five times about whether or not
3 Mr. Murphy shared off-label unapproved materials with doctors.
4 Not once, not twice, five times as documented in these
5 detailed notes about how long they knew Frank, what Frank does
6 in his discussions, asking questions about detailed messages.
7 These interview notes of multiple people that were not shown
8 to Ms. Kaucher document the details of this very important
9 investigation. Because what this Cesario investigation shows
10 is that, when someone raised their hand, when someone said
11 they thought something was going wrong, we investigated it.

12 There are documents that show this investigation, not
13 just of the people who work at Janssen, but of the doctors.
14 The investigation went to the doctor and said, The allegation
15 is someone is promoting off-label to you. Is it happening?
16 Is it true? And none of these were put in front of
17 Ms. Kaucher. Several times -- this was the Arnaldo Vega
18 interview. Here are the notes also not shown to Ms. Kaucher
19 that talk about the interview with Dr. Casey where Dr. Casey
20 was asked in detail about the particular studies that were
21 alleged to have been shared with her and that Dr. Casey said
22 no information was shared by Mr. Murphy, and she doesn't
23 recall him sharing any abstracts at all.

24 Relators' counsel asked Ms. Kaucher if Frank Murphy was
25 interviewed, suggesting that he wasn't. Nothing in this

1 document discusses that these allegations were even discussed
2 with Mr. Murphy. Do you even see a reference to Mr. Murphy?
3 But the notes had the documented interview with Mr. Murphy
4 right here. Of course he was interviewed. He was the subject
5 of the investigation. And here they were documenting the
6 conversation with Mr. Murphy, asking Mr. Murphy what had
7 happened, talking to Mr. Murphy about training and what
8 doctors he had visited and what studies were at issue.

9 And what is enormously telling about these documents
10 and what is enormously unfortunate is that they came after
11 Ms. Donna Graham had already testified.

12 And what these documents show is that Donna Graham was
13 untruthful. She was either untruthful with us in a health
14 care compliance interview, or she was untruthful with you when
15 she took the stand. Because she was interviewed as part of
16 this investigation. And she was asked, Frank Murphy, your
17 boss, is he promoting off-label? Do you have any concerns
18 about Frank Murphy? No, is what she said, outside of the
19 lawsuit when she was interviewed as part of her job, as part
20 of the health care compliance investigation. Discussions with
21 health care providers. This is about Frank Murphy as part of
22 her interview. He stays on-label and approved messages.
23 Doesn't recall him promoting off-label or answering any
24 off-label questions. Asked several times. That's what she
25 said during the investigation, but what she came in here and

1 said to you was that he may not have been the mastermind, but
2 he was directing her and others to promote off-label.

3 The other part of the investigation had to do with
4 whether or not Mr. Murphy had handed out studies for
5 educational purposes and not instructed the sales reps, This
6 is just FYI. Make sure this is just for educational purpose.
7 And one of the things that wasn't pointed out to you when this
8 investigation went up is the bottom of this investigation.
9 They absolutely found that Frank Murphy had not written on
10 these abstracts "education only." And you guys saw that a
11 little bit with Tim McSherry. If you remember some of his
12 emails, he likes to send out a lot of studies to his
13 colleagues, and almost every time he put, FYI, education only.
14 But there were some that he was shown where he said, I forgot.
15 I should have put it on there. No question.

16 That's what happened with Mr. Murphy, but when the
17 sales reps were interviewed, when the doctor was interviewed,
18 they had this conclusion: All of the sales reps -- except for
19 Cesario -- stated they were aware of the restrictions on
20 distribution of the material and that neither Murphy nor
21 Peterson had to provide them with those directions. And
22 that's consistent with what all of the folks said in the
23 interviews and what Mr. McSherry told you when he was here.

24 This is what these articles look like when they're sent
25 to the sales reps. They're stamped for "educational purposes

1 only." "Don't use in a selling situation." And you remember
2 seeing all these emails where they were being circulated with
3 that disclaimer. FYI, don't use in the field, and Mr.
4 McSherry told you when he sent these around, like when Frank
5 Murphy sent them around, the intention and the understanding
6 was not that people were going to go use them in the field.
7 They were educational. They were background. And that was
8 the conclusion of this investigation.

9 But Frank Murphy was still disciplined, even though the
10 sales rep said, We knew we couldn't use this in the field;
11 even though the doctor to whom he allegedly promoted off-label
12 said, He didn't use any studies with me; even though everybody
13 said, He stays on-label, he was still disciplined. He got not
14 only a verbal, written warning, but he was put on a
15 performance improvement plan. Because somebody reported an
16 allegation and Janssen took that seriously and investigated
17 this and interviewed people, not just in the company, but
18 outside, and found the truth, which is that there was no
19 off-label promotion going on, but for this infraction, for not
20 writing, FYI, he was disciplined.

21 I want to talk to you about the damages model in this
22 case, because I would suggest to you folks that the damage
23 model in this case that was put before you all to ask for
24 \$700 million shows what's really going on here.

25 Their damages expert testified twice. The only expert

1 in this trial to come back a second time is the one who was
2 calculating the money. He was here to ask for \$700 million
3 rather than putting on a rebuttal case with a doctor, with a
4 CMS expert, with a Plan D sponsor. They brought back the
5 damages expert to talk about his opinion.

6 Part of his opinion is that money should be paid to
7 certain states. What states and why? We do not know because
8 there is no evidence in the case. This evidence, does anyone
9 remember anybody talking about individual states and the
10 requirements for reimbursement? It did not happen. Donna
11 Graham said -- had signed in her declaration saying some of
12 these states, you know, medicines were ineligible for
13 reimbursement, and we asked her, like, what states and what
14 are the requirements? And she said she didn't know.

15 We asked Mr. Wilhelm, Each individual state has a
16 different requirement for what they're allowed -- what they
17 allow to be paid under Medicaid, and he said, Yes. I
18 understand that to be true. Yes. There are different
19 standards in each state about what is reimbursable. He said,
20 Those different requirements change at different times. But
21 there has been no evidence put before you all about what the
22 individual state requirements are. They have come in this
23 case asking for hundreds of millions of dollars, and there is
24 no evidence in this record about what the requirement was.
25 How do we know if a false claim was submitted anywhere if we

1 don't know what Mr. Wilhelm agrees exists, individual state
2 requirements?

3 Part of the millions of dollars that they are asking
4 for in this lawsuit is based on data that doesn't even
5 identify the doctor. You heard from Dr. Shaked about the ADAP
6 data. It does not allow you to know who the prescribing
7 physician was. We have no idea in this data if the physician
8 was contacted by Janssen or not. The claims, remember, are
9 that we caused a false claim to be submitted. We don't even
10 know in this data that underlines their damages if the doctor
11 ever had anything to do with us. That is the ADAP data, and
12 it is part of their damages model.

13 The pharmacy data, we don't even know who paid the
14 claims for some of this data. You heard from Dr. Shaked and
15 from Dr. Jena, CMS doesn't consider dose. When CMS is
16 deciding to reimburse the medicine, it does not have data on
17 once a day, twice a day, once a week, once a month. It does
18 not consider that as part of reimbursement. So they went out
19 and they put together a collection of bits and pieces of
20 pharmacy data, and some of it doesn't even tell you if a
21 government paid. It could have been Blue Cross. It could
22 have been some other private insurance. We don't even know.
23 This is the data that underlines -- underlines hundreds of
24 thousands of -- millions of dollars of requests for damages in
25 this case.

1 You heard about the assumptions that underlie Professor
2 Shaked's methodology here. He has put a damages model in that
3 says, If you were contacted by a Janssen sales representative
4 in 2006 and nearly ten years later, with no other contact in
5 between, you prescribed Prezista off-label. That's a false
6 claim. That is the model. Ten years later, nothing in
7 between, one sales call that we don't even have notes for, and
8 that is what they are coming to you saying is a false claim in
9 this case.

10 You heard about the way he takes prescriptions written
11 down the road by other physicians and attributes them to the
12 first physician. So instead of this prescriber, who we had
13 contact with, writing one prescription, Dr. Shaked says he
14 wrote 60. He says that's reasonable. It's part of the
15 damages model in the case. Dr. Shaked's model assumes that
16 anybody with a prior lipid condition is an off-label
17 prescription. And when we asked him, Well, what's that based
18 on, he said, Dr. Glatt.

19 But look at what Dr. Glatt said, "Prescribing Prezista
20 for someone with a lipid condition is not off-label.

21 "Correct. Nothing in the label says that this medicine
22 can't be used in a person with a lipid condition.

23 "It doesn't state that you can't use it in that
24 condition.

25 "Correct."

1 This is their expert. This is the only person they
2 claim was brought in to talk about some of these issues, and
3 he says it's not even off-label. That's Dr. Glatt. But this
4 assumption underlies Professor Shaked's request for hundreds
5 of millions of dollars.

6 Same here. Dr. Shaked has a theory that once a speaker
7 speaks, all of that speaker's prescriptions until the end of
8 time are false claims. Nobody from CMS came to tell us that
9 that's the rule. There's no document. There's no information
10 that the federal government does not want to reimburse.

11 When Dr. Ricky Hsu from the AIDS Foundation writes a
12 prescription for HIV medicine, this is the assumption that he
13 made up based on what the lawyers told him to assume. He
14 assumed once somebody speaks for Janssen, they can never get a
15 prescription reimbursed from the federal government again
16 because they're all false, under his model. That is his
17 assumption, and that underlies all of these hundreds of
18 millions of dollars that were put before you all this morning.

19 His "influence" definition comes from lawyers in this
20 lawsuit. There is no CMS testimony. There is no CMS manual.
21 There is no CMS rule that says the federal government does not
22 pay for prescriptions written by someone who has one visit
23 from a sales rep.

24 That's the evidence they would have to bring you in the
25 case to prove up what they're saying is true. If the federal

1 government doesn't pay when a doctor writes a prescription
2 because they got one visit from a sales rep or they spoke at
3 one event or they attended one event, where is the evidence of
4 that? They have the burden of proof, and they brought to you
5 nothing on this score. Nothing. No witness. No document.
6 No evidence.

7 They told us right here, this assumption comes from the
8 lawyers.

9 Same to you with this assumption that for the rest of
10 your life, if you're a speaker, the rest of your life it's a
11 false claim. Has anyone told these doctors? Has anyone told
12 these doctors if you get a visit from a sales rep, the
13 government's not going to reimburse another prescription you
14 write for the rest of time? There is no evidence that what
15 underlines -- underlies their damages model is true. They
16 simply have not made their burden.

17 Not only are you all going to have to determine if
18 these claims were false, which undisputedly they were not, and
19 there is no evidence in the record that they were, but they
20 would have to prove to you that something we did caused a
21 physician to write a prescription and get that submitted to
22 Medicaid and Medicare and other health care programs. And the
23 evidence is exactly the opposite.

24 The evidence in the case is that doctors make
25 individualized prescribing decisions based on what their

1 patients need. And this even came from Dr. Glatt, their own
2 expert. Doctors have to make individualized decisions about
3 how to treat their patients. It's not a one-size-fits-all
4 situation.

5 And you heard a lot of testimony from a lot of
6 different folks about how that's particularly true with HIV
7 medicines because HIV medicines are prescribed usually in a
8 group. You heard from Dr. Rosenberg and even Dr. Glatt about
9 a combination therapy, a cocktail of medicines, and you heard
10 about all of the different testing that goes into determining
11 what is the best medicine for someone with HIV. It's not a
12 situation where you can go into your doctor's office and get
13 an antibiotic and walk out of there with a prescription.

14 We heard from Dr. Rosenberg that all of these blood
15 tests have to be run so that a doctor can figure out the
16 mutations in the virus, the doctor can figure out other issues
17 that you might have going on with the disease, and the doctor
18 can make an individualized prescribing decision about what's
19 the best medicine for an individual patient. And that was
20 undisputed in this case.

21 Dr. Glatt agreed with it. Dr. Rosenberg agreed with
22 it. Every doctor that came in here agreed with it. That's
23 how HIV prescriptions are written.

24 And Dr. Glatt even admitted -- there's a lot of
25 testimony about Reyataz, and wouldn't it be better to put a

1 patient on Reyataz. Maybe in an individual physician's
2 opinion it might be. But Dr. Glatt admitted if you get that
3 blood work back and Reyataz -- your patient is resistant to
4 Reyataz, meaning Reyataz isn't going to work for them, it
5 would be medically inappropriate to write a prescription for
6 Reyataz.

7 It's not one size fits all. Doctors have to test the
8 virus and know about the patient's prior medical history and
9 side effects and figure out what makes the most sense.

10 Every one of the doctors that we brought in here to
11 speak with you, Dr. Hsu, Dr. Frank, Dr. McMeeking, Dr. Mills,
12 they all testified that prescribing decisions are made in
13 their own medical judgment. They are evaluating their
14 patients, and they are making their best medical decision
15 about what's right for the patients.

16 We heard it, too, folks, when we got the secret
17 recording of Dr. Turett. This is the doctor in that Nancy
18 Bartnett conversation where Ms. Brancaccio met -- you know,
19 secretly recorded. And if you recall, we played clips of it a
20 number of times throughout the trial, and he talks on that
21 tape about the reasons he makes prescribing decisions, and
22 it's got nothing to do with sales reps.

23 He talks about patient preferences. Personal
24 experience. Lab tests. Prior medications that a patient
25 might have failed on. The tape is about 45 minutes long, and

1 he explains all of the reasons why prescribers like himself
2 make prescribing decisions.

3 And you heard from real doctors who weren't being paid
4 by us, who had nothing to do with this lawsuit, who came in
5 here and said, I don't rely on sales representatives.
6 Dr. McMeeking said, "If I don't know more than a sales
7 representative, then I'm not doing something right. Hopefully
8 I know a heck of a lot more than any sales representative."

9 "Dr. Frank, you generally know more about these
10 medicines than they do?"

11 "Yes."

12 These doctors all told you sales reps might be a
13 resource for information, particularly back in 2006 when
14 getting on the internet wasn't as easy as it is today, but
15 these doctors know more about HIV and medicines than sales
16 representatives do.

17 And we have data that shows that these doctors are
18 making independent decisions. 2,000 of the, quote,
19 "influenced physicians" in Dr. Shaked's data never prescribed
20 off-label. So these are folks that, according to his
21 methodology, had one visit from a sales rep, one attendance at
22 a speaker event or one speaking event. 2,000 of these folks
23 never even prescribed in the way that they're claiming is
24 off-label in this lawsuit.

25 And, in fact, when you look at the highest prescribers

1 of these off-label indications that they're complaining about
2 in this lawsuit, the people who prescribed the most were
3 people who never had any contact with us.

4 So these are prescriber 1 and prescriber 2. If you
5 look at total off-label percentages on the far right, 63
6 percent of doctor number 1's prescriptions were off-label, and
7 59 percent of doctor 2. These folks had nothing to do with
8 us. Doctors write prescriptions based on what is best for
9 their patients, whether they see a Janssen sales
10 representative or not.

11 And Dr. Jena talked to you about how when you look at
12 the data in the appropriate way, when you control for
13 physicians being of the same type, physicians with one
14 indication, two indications, more than ten indications, there
15 is no difference in how physicians prescribe.

16 And you heard a lot this morning about Dr. Jena's --
17 what term he uses for causation, and there was some discussion
18 about whether it's the legal term or the economic term. But
19 he told you, because we asked him, "Dr. Jena, does it matter
20 what you call the term? Is there any other way to look at
21 this data?"

22 He said, "No. You could call it resulting. You could
23 call it direct cause. You could call it whatever you want.
24 But there is one way to do this evaluation. Substantial
25 factor, direct cause, resulting from, call it whatever you

1 want, but the process and the data is the same."

2 And when you compare apples to apples, not apples to
3 oranges, Dr. Jena showed you multiple times that the data
4 itself, forget the witnesses or the testimony, the data
5 doesn't show a difference.

6 He talked to you about an error that Professor Shaked
7 made that leads to that difference that he showed you. And
8 then you heard him say he's a hundred percent sure one of them
9 is wrong.

10 Let's talk a little bit about the government and how it
11 views reimbursement to these medicines.

12 Thank you guys for listening. I know it's been a long
13 day of people talking at you, but I appreciate the attention
14 even towards the very, very end of the case.

15 So this is a case about reimbursement from the
16 government. So let's talk a little bit about how the
17 government views reimbursement decisions.

18 We have a national policy in this country to make these
19 medicines available to people who need them. This is the
20 United States national HIV policy that says we must give
21 unfettered access to HIV patients who need HIV care. That
22 means, you need HIV medicine, the government, the national
23 strategy is, we don't want it to be difficult for those
24 patients to get that medicine.

25 And there's good public health reasons for that. And

1 Dr. Rosenberg and Dr. Glatt talked to you guys about that.
2 Because if you don't take your HIV medicine, you can become
3 resistant to the available treatment options. And if you
4 become resistant, you can be more likely to spread the virus
5 to other people who also are resistant.

6 And so it's not only in the individual patient that we
7 want to have access to medicine, but there is a public health
8 reason that we want people who need this medicine to get it,
9 so that they can take care of themselves and they can take
10 care of other people.

11 Nobody disagrees that these are terrific medicines. I
12 mean, there were very few things I think both sides agreed
13 about in this case, and you guys probably saw it, but this is
14 one of them. Nobody disputes these were great medicines.
15 They were fast-tracked approved by the FDA. They are
16 important lifesaving medicines, and the government recognizes
17 that.

18 The government guidelines, these are in evidence, they
19 are treatment guidelines for doctors. They don't work in
20 every single case, but they give recommendations about how
21 experts treating HIV should navigate some of these treatment
22 decisions.

23 Prezista and Intelence have been recommended in the
24 guidelines every single year since they were approved, and
25 Prezista was listed as a preferred protease inhibitor or a

1 preferred medicine in its class every year since 2008. And we
2 looked at those guidelines with Dr. Glatt. And one of the
3 reasons that Prezista and Reyataz were recommended as
4 preferred had to do with their lipid profiles because they're
5 both boosted with a hundred percent of ritonavir. And the
6 lower the ritonavir boosting, the less lipid effect that you
7 have.

8 So they are recommended by the government. You heard a
9 lot about these HIV medicines being in a protected class, and
10 here's why it's important for us.

11 We're not telling you they're in a protected class
12 because that doesn't mean the government doesn't want people
13 to break the law. That doesn't make any sense. They're in a
14 protected class because it's important for you all to
15 understand that that means that the government doesn't want
16 any barriers to people getting these medicines.

17 What do I mean by that? Because these medicines are in
18 a protected class, CMS says you cannot use utilization tools
19 when you're putting these medicines on your formulary. So CMS
20 tells the Plan D sponsors, who we never heard from in this
21 case, but it tells them, Here's how we want you to make these
22 medicines available. And what they say is when it comes to
23 HIV medicines, you cannot put in restrictions on how people
24 get these medicines. These are types of restrictions, step
25 therapy.

1 What does that mean? That means you can't say you have
2 to be treatment-experienced before I give you this medicine.
3 You have to have failed another step in the process before I
4 give this to you. CMS says no. You cannot put a step therapy
5 in place. Dose, once a day, twice a day, CMS doesn't even
6 consider that information.

7 Prior authorization. Like, do you have a prior lipid
8 condition? Let's check with your doctor. Absolutely not.
9 CMS says no.

10 These tools that CMS can use if it really wants to
11 restrict access to certain medicines, if it wants to kind of
12 double-check a doctor -- and maybe there are reasons with
13 certain medicines you want to do that. Opioids, maybe you do
14 want to double-check with the doctor that it's indicated.
15 Maybe you do want to know the quantity. Maybe you want a
16 prior authorization. Maybe. There are reasons with certain
17 medicines.

18 But one thing that is clear in this case and in
19 evidence when it comes to these medicines, CMS says no way.
20 You can't do any of that. These are HIV medicines prescribed
21 for HIV patients to treat HIV and that is what is important.

22 Critical for this case, and for you all as you sort
23 through the definition of what is false, Medicare Part D
24 covers off-label uses of medicines for medically accepted
25 indications. We know CMS pays for off-label uses, and there's

1 a couple of ways we know that, and we'll talk about it, but
2 it's right here in this document. Medicare Part D pays for
3 off-label. If it is medically accepted, it doesn't matter if
4 it's in the label or not, particularly in this class of drugs.
5 They want people to have this medicine.

6 Off-label does not mean false. And I would suggest to
7 you all that's how this case has been tried, suggesting
8 there's something wrong with off-label. That if you're
9 off-label, the government doesn't want to pay. That if you're
10 off-label, you're breaking the False Claims Act. That is not
11 the evidence, and that is not true. Off-label does not mean
12 false.

13 In fact, the government guidelines recognize that
14 sometimes the very best treatment in HIV is off-label. They
15 talk about how science of HIV rapidly evolves. And they say
16 information in these guidelines may not represent FDA approval
17 or approved labeling for the particular product or indications
18 in question.

19 Specifically, the term "safe and effective" may not be
20 synonymous or the same with the FDA-defined legal standards.
21 What do they mean? Sometimes we're making recommendations
22 that are moving faster than the FDA label.

23 And you heard that from many of the doctors, that
24 sometimes the doctors have access to information before it
25 makes its way into the FDA label. And if they, in their good

1 judgment, believe that that is appropriate for a patient, our
2 government wants them to get it and have it because, in
3 particular with HIV medicines, these drugs are saving people's
4 lives. We know CMS pays off-label, not just from the
5 document, but from the data. We know and we have the data
6 that almost 200,000 prescriptions off-label were written for
7 and paid for by prescribers who had nothing to do with us.
8 Almost 36 or almost 3,700 prescribers wrote nearly 200,000
9 prescriptions for medicines in these uses. Intelence once a
10 day, Prezista treatment-naive, all of the ways that these
11 Relators are complaining about, doctors who had nothing to do
12 with us wrote the prescriptions. The government reimbursed
13 the prescriptions, and nobody is claiming that the government
14 should get that money back. Nobody in this lawsuit is saying
15 there's something wrong with the government having paid for
16 those prescriptions.

17 Dr. Glatt told us medically appropriate includes
18 off-label. "In your medical judgment, it was medically
19 appropriate to prescribe the medicine off-label.

20 "It can be. Yes. And it has been. And, in fact, that
21 happens a lot in the area of HIV.

22 "Would you agree?

23 "Yes. It happens a lot in medicine."

24 And Dr. Glatt -- we heard a lot about Dr. Glatt this
25 morning and what he thinks is or is not appropriate. But take

1 a look at these -- this testimony.

2 "There are certain conditions in which it is medically
3 appropriate to prescribe Prezista to someone with a lipid
4 condition?

5 "I agree with that, yes. Limited number of conditions.

6 "There are certain -- patients for which it is
7 medically appropriate to prescribe Prezista to a naive patient
8 before it made its way into the label. Dr. Glatt, your
9 opinion is that it would have been appropriate for a physician
10 who had knowledge to prescribe Prezista to a naive patient
11 before it came into the label?

12 "Yes."

13 And he said the same thing about Intelence naive. He
14 spoke to you all when he was here about a particular mutation,
15 K103N, and he said, in that situation, if a naive patient had
16 that mutation, I would prescribe it off-label. Doctors make
17 these prescribing decisions in their independent medical
18 judgment, and the government reimburses for it. And there's
19 been no information in this case that would suggest otherwise.
20 Dr. Rosenberg gave the same testimony about this K103
21 mutation.

22 Let's talk about how Janssen promoted these medicines.
23 We properly promoted Prezista and Intelence to doctors. I
24 will not bore you with the policies that you all saw a
25 gazillion times during the course of this trial. There's no

1 dispute we have extensive policies that ensure on-label
2 promotion, proper compliance. Ms. Evans, when she was here,
3 she said, Yes. The policies on their face she has no problem
4 with. And these policies are going to be real important for
5 you as you work through the jury instructions as you think
6 about this case because the allegations in this case are that
7 we knowingly or willfully violated these statutes. We had
8 policies in place to intentionally make sure that we were not
9 doing and our employees were not doing the very things that
10 are being complained about here. Everyone agrees, all of the
11 fact witnesses who testified agreed that we have policies that
12 prohibited off-label promotion, and you even heard a little
13 bit about the individual pledge of ethics that these sales
14 representatives signed to say that they pledged that they
15 would abide by our policies and that they would not promote
16 off-label and that they would adhere to the policies.

17 What is critical for the allegations in this case is
18 this: The government was looking at this during the period of
19 time at issue in the case. As part of the corporate integrity
20 agreement, our promotional activities, including the very ones
21 that are being critiqued and allegations are being made about,
22 the government was checking them and monitoring them. These
23 are just a couple of things from the CIA that the government
24 monitored that had to get updates on, cold plans for sales
25 representatives, the independent organization had to look at

1 those promotional materials, medical information requests, all
2 of the things that they're complaining about here, the United
3 States Government, as part of these CIAs, in connection with
4 an independent third party, was looking at it.

5 When Ms. Evans was here she said, Yes, there are
6 significant things the government could do to punish Janssen
7 if, when it looked at all those things, it decided Janssen
8 wasn't in compliance. She said, Yes, you could get stipulated
9 penalties, and there's no evidence the government subjected
10 Janssen to stipulated penalties. She said, Yes, you could be
11 excluded from federal or state reimbursements, and there's no
12 evidence of that either because Janssen complied with the
13 requirements under these CIAs, and the jury instruction shows
14 that you can consider that as it goes to our intent. Did we
15 do something knowingly and willfully and improperly when we
16 were complying with what the government told us to do as part
17 of a CIA? That's not going to make sense. How could we
18 willfully violate the Anti-Kickback Statute when the
19 government was checking on speaker programs? Our speaker
20 program policies, our training decks, our criteria for getting
21 a speaker on the board, how could we willfully do that when
22 the government was checking it and the government has the
23 power to punish us and did not?

24 Let's talk a little bit about the promotional materials
25 that were submitted to the FDA, draft materials under subpart

1 H. Every single one of them went before we used it. Amit
2 Patel explained two different regimes by which promotional
3 materials are submitted to the FDA. Subpart H is before you
4 get the complete label. That's where you have the early
5 access label.

6 "When we were under subpart H, did we ever use a piece
7 that didn't first go to the FDA.

8 "No. After we were out of subpart H, we operated under
9 2253."

10 And there was a lot of testimony and there's a jury
11 instruction about how 2253 works. The only witness who came
12 in here who worked at the FDA and who has practiced
13 implementing 2253 and liaising with the FDA was Dr. Patel.
14 And he told us how 2253 works. There is no such thing as an
15 approval letter that comes from the FDA under 2253. It
16 doesn't exist. And the jury instruction is going to say that.
17 There is not a regulation that deals with silence from the FDA
18 or approval from the FDA as it relates to this 2253 process
19 that Dr. Patel was telling you about.

20 We asked him, "It sounds like an approval letter is not
21 an option."

22 And he said, "That's right. That is how 2253 works.
23 The government does not send an approval letter.

24 "But enforcement is an option.

25 "Yes. That is how the government responds. That is

1 how FDA responds if they have comments or they have problems
2 with what you submit under 2253. No approval letter, but you
3 could get an enforcement letter or you could get nothing."

4 We sent all of the internally approved messages that
5 were going to be used in the sales force to the FDA. They're
6 in evidence, and they include messages that had to do with
7 lipids. Proven lipid profile with all of the graphs and all
8 of the data in the background was packaged up and sent to the
9 FDA as part of 2253.

10 And we sent consumer pieces as well, and you saw the
11 feedback we got on a consumer piece. And what's important
12 when you're analyzing this data -- look at the consumer piece
13 on the right. What we had proposed -- and this piece was
14 never used -- was to make one little bullet that says, "low
15 impact on cholesterol." No graph. No data. No cite.
16 Nothing.

17 And the FDA, rightly, if you ask Dr. Patel, said,
18 There's not enough information there. That could be confusing
19 to a consumer. They won't know how to interpret low impact on
20 cholesterol.

21 And Dr. Patel told you he spoke to the reviewer at the
22 FDA about that feedback. And what the reviewer -- what he
23 understood speaking to the reviewer is that you have to
24 provide the data, and the only audience who can understand
25 that data is a doctor. We can't put charts about the national

1 cholesterol cutoff in consumer pieces. We can't put all of
2 these laboratory values in a consumer piece because that
3 wouldn't be fair to a consumer. It wouldn't be easy for them
4 to understand.

5 But when you put it in a health care provider's piece,
6 which you are required to give to the doctor with the label,
7 then it has context. Then it is not false and misleading.

8 And we know that the FDA is looking at this stuff when
9 it comes in to them under 2253 because one of our competitors
10 got an enforcement letter just at the same time we were
11 sending all our stuff to the FDA. And you remember this came
12 into evidence with Dr. Patel. Hoffmann-La Roche sent
13 information about lipid messaging and other messaging to the
14 FDA, just like we did, under 2253, and the FDA issued an
15 enforcement letter.

16 And they said, We think parts of this are misleading.
17 Put more information here. Change the font there. They gave
18 feedback. That's the way the process works. We know that
19 because it happened to Hoffmann-L Roche.

20 But Dr. Patel said he never got a letter like that. We
21 sent our data just like Hoffmann-La Roche did, just like we
22 did on the consumer piece where we did get feedback, and we
23 got no feedback or enforcement letter on the lipid pieces.

24 When the FDA gets a 2253 submission that it doesn't
25 agree with, it issues a warning letter. It issues an

1 enforcement letter. And Dr. Patel explained, based on the
2 feedback we got on the consumer piece, based on his
3 understanding from discussions with the FDA, based on the data
4 we submitted to the FDA contextualizing all of that scientific
5 data, that these pieces were approved internally, and, we
6 believed, approved by the FDA as well.

7 And you saw the request for admission from Ms. Penelow
8 and Ms. Brancaccio. They knew these were approved pieces to
9 go out into the field. They knew minimal impact, low impact,
10 proven lipid profile, they had all gone through Janssen's
11 Promotional Review Committee. They had all been submitted to
12 the FDA on 2253. They were approved by Janssen to use. But
13 the claims here are that while all of these were okay, low
14 impact, minimal impact, proven impact on lipids, lipid
15 friendly is somehow different and constitutes fraud on the
16 government.

17 Using an adjective like "friendly" does not make a
18 claim false. You heard testimony from multiple people,
19 including Dr. Patel. Sales representatives are not required
20 to read word for word off of a product label. They are not
21 required to read word for word off of an approved piece. They
22 are required to deliver messages consistent with the approved
23 piece, consistent with the label and consistent with the data.
24 Using an adjective like "friendly" instead of minimal, proven
25 lipid profile instead of low impact on lipids does not make

1 the claim false.

2 And, in fact, you heard from their own witness, one of
3 the friends who came in to testify, he actually thinks lipid
4 friendly is the most accurate of all of those terms.

5 "You said more lipid friendly is probably the better
6 terminology to describe Prezista, right, sir?"

7 And he says, "When you talk about different phrases, I
8 think more lipid friendly would have been the most accurate."

9 That's the testimony from their witness.

10 And, again, Dr. Glatt conceded, as he had to, these are
11 not off-label messages. There is nothing in the Prezista
12 label that says you cannot use it in somebody who has a lipid
13 condition. It's not off-label, and their own expert,
14 Dr. Glatt, admits that.

15 There was a suggestion yesterday with Dr. Mills, sort
16 of "Why are you coming in here? We don't understand what this
17 exercise is all about." They have alleged that we
18 participated in a nationwide conspiracy that involved these
19 doctors, that our sales representatives went into doctors'
20 offices from New Jersey to California and repeatedly and
21 continuously promoted off-label. And we brought you not one,
22 two, three, but four doctors, some of the doctors who had the
23 highest number of visits from sales representatives.

24 Dr. Hsu and Dr. Mills are top of the list in terms of
25 doctors who had frequent contact with sales reps, and they

1 told you it never happened. They do not believe anybody was
2 in their office delivering these messages.

3 Dr. Hsu has a memory of Ms. Penelow specifically. And
4 we asked him specifically, "Well, didn't Ms. Penelow come in?"
5 She didn't. The sales representatives did not promote to
6 these doctors off-label because there was no nationwide
7 scheme. And if it really happened, where are the doctors? If
8 what they are saying in this lawsuit is true, where are the
9 people to dispute the four doctors we brought you? Where is
10 the doctor, not a speaker, not someone affiliated with us, a
11 regular doctor who got a visit from a Janssen's sales rep. If
12 this really happened, they'd be in here supporting this case.
13 And they are not because it didn't happen.

14 Let's talk about the anti-kickback claim. We did not
15 bribe doctors, and that's what the evidence shows. This claim
16 did not originate with Ms. Penelow and Ms. Brancaccio. That
17 is not a trick. That is not a defense. That is the evidence
18 in the case that is going back to you in the jury room.

19 That's what this email shows. They are on the eve of
20 filing their complaint, and they think, as an afterthought,
21 let's add the kickback claim. Let's find some fancy
22 restaurant pictures and throw it into the complaint. That is
23 the truth of what the evidence is before you all.

24 You heard that we have a broad speaker program, some of
25 which has nothing to do with individual medicines. 2,000 --

1 almost 2,000 of these programs you can't even -- excuse me --
2 you can't even mention the name of a medicine. Disease
3 awareness, community speakers' bureau, all of those programs
4 are just about HIV. They're just about education on
5 scientific topics. They don't even mention brand names.

6 There was a suggestion that we had a lot of speaker
7 programs, but consider the data. We are talking about two
8 different product over eight label changes; 11 times the
9 guidelines changed over the course of nearly a decade. And
10 these programs covered almost every single state in the
11 United States with 300 or 335 speakers. When you do the math,
12 it's like one program a state a month. These programs were
13 not multiple times a week, back to back. These were an
14 appropriate number of programs for the changes in the label
15 and the length of the time period that this program won -- or
16 ran.

17 Importantly, this was another area that the government
18 was checking. This was another area that was part of the
19 corporate integrity agreement and cooperation. These are just
20 some of the areas that the independent third party was
21 checking and reporting to the government. Qualification of
22 speakers. Speaker venues. Needs assessments.

23 Remember you saw those documents about why we had a
24 need for programs? The government, the IRO was looking at it.
25 The training documents. The speaker criteria. Everything

1 that is being alleged here to have led to a violation of the
2 law was being looked at by the government who enforces the
3 law.

4 We have a promotional speaker bureau policy that is
5 tailored to making sure we are not violating the Anti-Kickback
6 Statute. This is not a situation where we don't know.
7 Payments to health care providers can be subjected to scrutiny
8 under the anti-kickback law. For this reason, the bureau has
9 to undergo a critical review by the SAFE committee.

10 And you heard every friend who testified made
11 allegations about speakers getting on the bureau or coming off
12 of the bureau or tracking speakers. None of them were part of
13 the selection criteria, and they all admitted it when they
14 were here.

15 Sales representatives could only recommend speakers.
16 They could not make a decision to put a speaker on the bureau,
17 and they could not make a decision to take a speaker off the
18 bureau. By design, the sales representatives were kept out of
19 that process. They made recommendations to a team. It went
20 through the SAFE committee up until 2010, and after that,
21 compliance fulfilled that role. They were purposely kept out
22 of this.

23 You saw the criteria in our policy that we used to
24 evaluate folks on the speaker bureau. And as you would
25 imagine, one of those criteria is experience with the product.

1 And all of the doctors that came in here to talk to you said,
2 Of course. You can't have someone speaking on the bureau
3 who's never used the product, who can't anticipate questions,
4 who can't talk about his or her experience.

5 And you saw in real life how we evaluated that in
6 everyday documents. This is one of the Excel spreadsheets
7 that listed all of the speakers and then ran their
8 qualifications through multiple rows: Had they published?
9 Had they investigated? Were they part of any presentations or
10 grand rounds?

11 You saw in actual practice how people were evaluated
12 according to these independent criteria, not according to
13 prescriptions.

14 And to be perfectly clear, we have -- we have
15 prescription data on all doctors. This is not a secret, and
16 there is nothing wrong with it. And, of course, you see all
17 these charts: New England speakers, top ten speakers, and it
18 has prescription data for speakers. Of course. Everybody has
19 it. Having prescription data on speakers is not a violation
20 of the Anti-Kickback Statute. What we are not allowed to do,
21 and what the evidence showed we did not do, is analyze whether
22 paying a speaker to speak at an event causes that speaker to
23 increase his or her prescriptions. You can't do an analysis
24 of that.

25 And there were a bunch of documents that were shown to

1 you all to try and suggest we were doing that, backup PLM
2 data, some sort of interpretation of decks. Every witness who
3 had responsibility -- Deb Kenworthy, Candice Long, Kim
4 Saladana -- told you that was not an analysis that Janssen
5 did, and you didn't see any document that shows that analysis.
6 You heard lawyer interpretation of backup charts. There is no
7 return on investment analysis for speakers following a speaker
8 program by design.

9 Ms. Long and Ms. Saladana, you heard, sort of ran the
10 speaker bureaus or had a leadership role for the speaker
11 bureaus for Prezista, as it relates to Ms. Saladana, and
12 Intelence as it relates to Ms. Long. And they told you, of
13 course, what the documents show. Prescriptions were not a
14 criteria for selection on the bureau.

15 And maybe some of the best evidence of this was Ricky
16 Hsu's testimony, because he was real candid. He said, Look,
17 actually, I did get removed from another company's speaker
18 bureau because I wasn't using the medicine anymore and it
19 didn't make any sense. I didn't feel comfortable.

20 But he said when he came to our speaker bureau, his
21 prescriptions increased and decreased depending on his patient
22 population at the time and his participation on the bureau
23 never changed.

24 Ricky Hsu gave you his firsthand experience with
25 whether or not prescriptions drove participation, and he told

1 you it had no effect. You saw the contracts with multiple
2 speakers. These contracts had the doctors certify that they
3 weren't being bribed. There is a section in these contracts
4 that says, "We are going to pay you fair market value, and you
5 are not to view your participation as requiring you to
6 prescribe more of our medicine."

7 That is evidence that we were not willfully violating
8 any law to find us as having violated the Anti-Kickback
9 Statute. You have to find that we did it willfully, knowingly
10 and willfully. But you saw the policies. You saw the
11 practice, and now you see the contracts where we specifically
12 had the speakers agree You understand, Speaker, this is not a
13 bribe. And everybody agreed to that.

14 They received fair market value. They used locked
15 presentations that we had a third party hold on to to make
16 sure we were adding an extra layer of compliance.

17 You've seen these speaker agreements. They also go
18 through requirements to stay on-label.

19 Ms. Evans agreed there was nothing improper about the
20 amounts we were paying the speakers to speak. The honorarium,
21 she said, industry standard and did not raise a violation or a
22 compliance concern. That's not an issue. The thousand
23 dollars, \$2,000, that was the compensation for getting ready,
24 speaking. Even their own expert has no issue with that.

25 You saw repeatedly a handful of pictures from a number

1 of places where speaker training was held, but you saw the
2 documents that show that these were vetted through compliance.
3 Not only was this cleared by compliance, as you can see in the
4 email, but it was selected because they were able to negotiate
5 a manageable price for all of the people that they had to have
6 there.

7 We were not willy-nilly selecting fancy places to hold
8 these events. They were compliance cleared, and they had
9 negotiated prices to keep the amount of money being spent per
10 person within the guidelines.

11 You heard from all of these physicians that none of
12 them perceived an invitation to be on the speaker bureau to be
13 contingent upon prescribing more. You heard from all of them
14 that they would not have participated if they thought that
15 somehow doing so meant they had to prescribe a certain number
16 of prescriptions.

17 And Ms. Evans conceded she's not aware of any statement
18 by any physician that would suggest they were influenced by
19 the money that they received from Janssen as an honoraria or
20 for other reasons to prescribe the product. This is their own
21 expert's concession. No evidence from the physicians.

22 There was discussion about these PILM documents. There
23 are, like, 300 of them moved into evidence. They all talk
24 about analyses of the participants. It is a promotional
25 speaker bureau. The participants are not getting paid. Part

1 of the goal is to have a speaker present education so the
2 participants know more about the medicine and maybe they
3 prescribe it where appropriate. And we did analyses of
4 whether that was working, whether that made sense, whether we
5 should keep doing that.

6 These analyses were overseen, and Deb Kenworthy was
7 involved. She was the only witness who testified who had any
8 involvement with these PILM documents, and she told you the
9 speakers were not included in these calculations. That is
10 uncontested evidence because nobody else was involved in these
11 PILMs.

12 And, in fact, Sara Strand, when she was here, was shown
13 one of her emails where she says the best practice is to
14 evaluate whether your program is having an effect on the
15 participants. She testified it's -- nothing wrong with
16 tracking whether or not your speaker program is effective.
17 And if you look in the email, she says, "Below is an example
18 of a best practice. A return on investment for the
19 participants."

20 You also saw emails and heard testimony about speakers
21 being removed from the bureau, not because of prescriptions,
22 not because it was part of a bribe, but because they weren't
23 following the rules, because they weren't agreeing to be
24 compliant.

25 This was emails you saw about a Dr. Marsh, who was not

1 happy not promoting off-label. Dr. Marsh has made it clear
2 he's not interested in participating if he can't speak
3 off-label. We kicked him off the speaker bureau. That is
4 what you would expect from a company that has rules in place
5 to make sure that these programs are run in an appropriate
6 manner to comply with policies and to be mindful that we are
7 not violating the Anti-Kickback Statute.

8 You saw this compliance deck a bunch throughout the
9 trial. And here is what I would suggest to you is real
10 telling. There are examples in here of companies that got in
11 trouble for real anti-kickback violations, and just look at
12 them. The first involved sending a doctor and a guest to
13 France in exchange for a certain number of prescriptions.
14 That is a violation of the Anti-Kickback Statute. There are
15 no allegations in this case that any spouse came on any of
16 these trips. No allegations in this case that we exchanged
17 speaker participation for a particular number of prescriptions
18 like was done here.

19 Look at the second one. Bribes through unrestricted
20 grants. Doctors were given \$65,000 to do whatever they wanted
21 with. There are no allegations that that happened in this
22 case. Nobody is even taking issue with the amount, the fair
23 market value that was paid to compensate speakers for their
24 time.

25 And there is certainly no allegation that we were

1 giving, unrestricted, hundreds of thousands of dollars to
2 speakers to do whatever they wanted with.

3 These are the examples in these compliance decks that
4 you saw so many times throughout the trial.

5 Janssen did not violate the Anti-Kickback Statute. We
6 have policies in place. We had government entities and an
7 independent third party checking our policies. These are
8 examples that are not like the facts of this case.

9 Great news. This is my last topic. We are at the end,
10 and you guys have been terrific. So thank you again for your
11 attention.

12 One of the things you do not have to leave at the door
13 when you come to jury service is your common sense. And what
14 is being alleged here does not make common sense. As you just
15 think about these allegations of a nationwide conspiracy
16 during the time period the government was checking on us, it's
17 not going to make any sense. Think of all the people who
18 would have had to have been involved in this. All of the
19 5,100 doctors that we visited who didn't come into the
20 courtroom to support this, that means there are more than
21 5,000 doctors out there who believe they were promoted to
22 off-label for a decade and they didn't bring you one of them
23 to come in here and say that that was true.

24 Doctors would have had to be in on it. Institutions
25 would have had to be in on it. The entire sales force would

1 have had to be in on it. Everybody they brought in knows each
2 other. It's a group of seven people, two of whom stand to
3 receive a significant financial reward in this case, two
4 others who filed their own lawsuit that got dismissed for a
5 significant financial reward, and the other three who are
6 connected with them.

7 You heard from Ms. Strand, who was the highest ranking
8 of all the fact witness. She had sort of the highest
9 position. She was a regional business director. And she
10 admitted there was no instruction to promote off-label. This
11 conspiracy was not carried out in writing, Ms. Strand said.
12 But she also said there was no verbal instruction. This
13 conspiracy that they're alleging, no writing, no talking.

14 And then Mr. Wilhelm sort of said how it had to go
15 down. It was carried out with a wink. That's what he said.
16 Everybody said no documents, no instructions, it must have
17 just been like a wink, that apparently 150 sales reps got the
18 wink except Steve Samachia, who Ms. Penelow testified, Well,
19 at least Steve Samachia wasn't promoting off-label. But
20 everybody else in the country understood from a wink, not an
21 instruction, not anything written down, that they, for a
22 decade, were supposed to promote off-label? It doesn't make
23 common sense.

24 Ms. Evans talked to you about the responsibility of the
25 doctors under the bad ad program to report if something like

1 this was going on. These allegations are not just New Jersey,
2 just the East Coast. These allegation are nationwide for
3 almost a decade involving thousands of doctors, and not one of
4 them reported it as they are obligated to do by FDA
5 regulations? It doesn't make sense.

6 This is just the list of doctors in the New York
7 district that Ms. Brancaccio visited in one year. It's not
8 going to make sense that this happened and they didn't bring
9 to you anybody who could support the claims.

10 Ms. Evans conceded she never heard of any doctor
11 reporting what's being alleged here.

12 Where's the New York team? This was the New York team
13 just from one year. The only people that came in here all had
14 a lawsuit for a lot of money. Where are the people who truly
15 have nothing to gain from the New York district? They did not
16 come in to support this claim.

17 You heard from Nancy Bartnett and Tim McSherry, who are
18 from the New York district, and both of them told you this
19 never happened. Mr. McSherry worked alongside Ms. Penelow and
20 Ms. Brancaccio for many years in New York. He when -- he had
21 the same managers. He visited the same doctors. He told you
22 there was no instruction to promote off-label. He did not
23 promote off-label. The allegations that are being made here
24 are not truthful and accurate.

25 You heard from current and former employees, folks like

1 Deb Kenworthy who are reviewing data from physicians across
2 the country, Mike Iacobellis, who directed the sales team for
3 many years. You heard from Megan McGrath, HR, Kim Saladana,
4 Candice Long, all of these different executives, many of them
5 no longer with the company, who told you there is no support
6 for the allegations being made here.

7 And this is the part that just doesn't make sense.
8 They weren't only promoting Prezista and Intelence. This
9 sales force was promoting other HIV medicines, Edurant and
10 Complera. But the testimony to you all was that they weren't
11 promoting those off-label. Just Prezista and Intelence.

12 That doesn't make sense. They had the same managers,
13 the same colleagues, going to see the same doctors, receiving
14 the same training and they were instructed just to promote
15 these two off-label but not the other two?

16 And there was some suggestion, Well, these other ones
17 had better labels so we didn't need to. Any medicine could be
18 promoted off-label if that's true. Why would this conspiracy
19 only apply to two medicines of the four medicines they're
20 going to visit?

21 Plaintiffs, Relators and Relators alone, have the
22 burden of proof here. They have got to prove to you now at
23 the end of six weeks that it is more likely than not that they
24 can put enough evidence on that scale to get it all the way up
25 to more than 51 percent, to prove to you that it is more

1 likely than not that we knowingly violated the False Claims
2 Act, when we have no evidence from anybody who was in charge
3 of submitting those claims to CMS, when we have no evidence
4 from CMS itself that we wilfully violated the Anti-Kickback
5 Statute when the government was checking on our speaker
6 program? They have not come close to meeting their burden in
7 this case, and this case is not about the government.

8 You heard the Court instruct you the Department of
9 Justice is not involved in this case for this trial. This is
10 not about the government. The government was checking on all
11 of this. It had the ability to kick us out of Medicare if
12 what they are alleging was true, and it didn't do that. It's
13 not a case about the government.

14 Because we are the defendants, because we got sued, we
15 don't get a rebuttal. So I'm going to sit down, and it's the
16 last time I'll get to talk to you all. But the Relators get
17 to come back and talk to you a little more and talk about some
18 of the things I said. And I hope that when they do that, they
19 can answer some of these questions for you. Because I can't
20 come back.

21 Why didn't they bring a single witness from CMS? You
22 are being asked, as part of what you're evaluating, to
23 determine that CMS would not have wanted to pay for
24 prescriptions written by somebody who had one contact with
25 Janssen.

1 Where is the evidence to support that? Why did no one
2 from CMS come in here to talk about their eligibility
3 requirements, their reimbursement?

4 Where is the Plan D sponsor? What about a Plan D
5 sponsor who could tell you who they are, how many of them
6 there are, and what they do to determine if a medicine or a
7 prescription should be submitted to CMS? No evidence in the
8 case. Why not? How did they do it?

9 Why didn't they bring you a single prescribing doctor
10 if this went on for as long as it did all over the country?
11 Where's the doctor to support that?

12 I hope they tell you how the government could miss a
13 nationwide conspiracy while carefully monitoring our
14 promotional activities. And the answer is not that there were
15 two CIAs, because the conduct at issue in those CIAs took
16 place a long time ago. Well, before the time period of this
17 case.

18 How could the government have missed it and
19 Ms. Brancaccio and Ms. Penelow have discovered it? And what
20 states are defrauded and what evidence did you hear about any
21 individual states and how they make reimbursement decisions?
22 How could we have violated False Claims Act states -- False
23 Claims Act in each of these individual states when their own
24 witness testified that they have different requirements? And
25 we don't know what they are because they didn't come into

1 evidence here.

2 Thank you all very, very much for your attention during
3 the entire trial and particularly today as I am hour five and
4 six of people speaking at you, but I really appreciate it.

5 Thank you very much, Your Honor.

6 THE COURT: Thank you, Ms. Brown.

7 Folks, we are taking a ten-minute recess.

8 THE DEPUTY COURT CLERK: Please stand for the jury.

9 (The jury exited the courtroom.)

10 THE COURT: You all can have a seat.

11 Mr. Marketos, you have about 30 minutes, you said?

12 MR. MARKETOS: Yes, Your Honor.

13 THE COURT: All right. Do you want to take ten
14 minutes? You don't have to start yet.

15 MR. MARKETOS: No. I'll take the ten minutes. Thank
16 you, Your Honor.

17 THE COURT: All right, folks. We'll see you in a
18 bit.

19 (A short recess occurred.)

20 THE COURT: Mr. Marketos, are you ready to go?

21 MR. MARKETOS: I am, Your Honor.

22 THE COURT: All right, Patti, let's get the folks and
23 close this out.

24 By the way, there's no concern there. I know I spoke
25 off the record briefly about what I'm going to instruct the

1 jury to do, but is there any concern from either side?

2 MR. MARKETOS: No, Your Honor. Thank you.

3 MS. BROWN: No, Your Honor. Thank you.

4 THE COURT: All right.

5 THE DEPUTY COURT CLERK: All rise for the jury.

6 (The jury enters the courtroom.)

7 THE COURT: All right, folks. Everybody have a seat,
8 and we're going to continue with the rebuttal argument.

9 Mr. Marketos, whenever you are ready, you may proceed.

10 MR. MARKETOS: Good evening. Well, I have a lot to
11 address. Look, I took a lot of notes during that response
12 from Janssen. And I had -- I had Whitney Wendel ready to help
13 me out, and I had Josh Russ ready to get me some testimony. I
14 had Andrew Wirmani ready to find something in the record. I
15 had everything ready to go. I really did.

16 And, boy, I was going to say, wait a minute. Now the
17 government was monitoring? The government was monitoring.
18 You started the trial, and the issue was, how could this
19 possibly have happened? And we would never be having a
20 nationwide scheme like this. And we said, what are you
21 talking about? You did it twice and you got caught for it
22 both times.

23 And then when we made that point during the trial, now
24 during closing argument, Janssen gets up and said, how could
25 we have done it, the government was watching us because we got

1 in trouble and they were monitoring our activity. So they
2 were babysitting us. So we couldn't have gotten caught.

3 You follow the argument?

4 First it was we wouldn't have done it. We said, You
5 did do it, and you did it again and you did it again.

6 Then they said, Well, no, then we couldn't have done it
7 this time because they were watching us.

8 It's the kind of stuff that you just -- you just had to
9 stop for a second and say, okay. Okay. This is why we have
10 juries. This is why we have dozens of years from the school
11 of life and the university of hard knocks in this box. Using
12 your judgment to weigh people's arguments. Because it is not
13 possible in 30 minutes to unpack new arguments that are
14 completely the opposite of what Janssen told you at the
15 beginning of the case. We have -- I'll just give you one
16 example.

17 "We had an independent review organization that was
18 monitoring our behavior." You just heard that from Janssen's
19 counsel. "So we could not have been engaging in this bad
20 activity."

21 First and foremost, that's like saying, we couldn't
22 have committed a crime because we were on probation already.
23 I mean, does that make sense to anybody? Right? Just to
24 begin with.

25 Second, that started in 2010. It started in 2010.

1 This activity began in 2006. So for four years, how was an
2 independent review organization monitoring your activity from
3 2006, 2007, 2008, 2009, 2010? How did that happen?

4 Second -- third or fourth, I'm not sure which -- why
5 didn't you call the independent review organization to come to
6 the stand and say none of this stuff was going on? That's an
7 agency that Janssen hires, okay, to tell the government that
8 it's complying with the corporate integrity agreement.

9 And if a corporate integrity agreement could stop you
10 from doing it again, why did they get another one in 2013 for
11 a different drug? For a different set of nationwide,
12 off-label sales and kickbacks? Why did it happen if the -- if
13 by virtue of having a corporate integrity agreement in place
14 stopped you retroactively from doing this -- it's just too
15 difficult to unpack. And at some point we have to say to
16 ourselves, look, they have to understand now why it's taken 12
17 years to get to this place. Why it's taken 12 years.

18 Why has it taken 12 years? Because they argue with
19 everything. They change their position. If you catch them on
20 something, they go somewhere else. It is like trying to kill
21 a zombie in a movie, in a bad movie, and it keeps coming back
22 to life. And what I mean by that -- I'll just give you
23 another example. I'll give you another example.

24 Where is the evidence -- where is the IRO to testify?
25 Here's another one. Ms. Strand had a changing story. Here's

1 another one. Donna Graham had a changing story. They were on
2 the witness stand for days. They told you everything. Donna
3 Graham's declaration is in evidence. We've told you the
4 number of it. You're going to be able to read it, if you want
5 to.

6 But they'll find something to say, Well, they had this
7 issue over here so just ignore all of it. This is all made
8 up. And they drew the lines again.

9 I even wrote one down. Mr. Grooms is connected to
10 Ms. Strand. They worked together. Ms. Grooms -- Mr. Grooms
11 and Ms. Strand are connected because they worked together.
12 Yes, everybody worked together. Everybody worked together at
13 Janssen. So if they come into court and tell you this is what
14 Janssen was doing, ladies and gentlemen of the jury, you
15 should not believe it happened because they were working
16 together? That's the point.

17 So we can't call employees who witnessed everything
18 that was going on to tell you what was going on because they
19 worked together. And if they leave Janssen, now they're in
20 cahoots. It doesn't matter what part of the country they're
21 from, how connected they are at all. It's just impossible to
22 catch Janssen. That's what they're going to tell you.
23 They'll do it every time.

24 They just think that never on judgment day were they
25 going to be facing two former sales representatives in a

1 whistleblower lawsuit and eight members of the public. Eight
2 jurors of theirs peers to judge them. And it is everything
3 they can do to change the story.

4 I have -- I have the opening statement that Janssen
5 gave to you. We scanned it. We can put it up on the screen.

6 Would you do that, please, Ms. Johnson?

7 What do you think the likelihood is if we scrolled
8 through the opening statement that you will find anything
9 about we had an independent review organization watching over
10 us? When the trial started, did Janssen say, this could not
11 have happened because we had an independent review
12 organization watching over us? No. They told you these
13 messages were FDA approved. Right?

14 So we go about disproving that. We put Mr. Patel on
15 the stand. We call them. We show you that they never had any
16 FDA approval. We get an instruction from His Honor that's in
17 your instructions that says FDA silence. Okay? There's no
18 statute that says FDA silence is approval. We can't do better
19 than that. We can't do better than calling their witness,
20 proving it was false, proving they had had no approval.

21 So now what is the argument? We had an independent
22 review organization watching us appointed by the government in
23 2010, so we couldn't have done it.

24 Let's scroll through the opening statement. Do you see
25 anything from when the trial began about how they could not

1 have done it because there was an independent review
2 organization? Top to bottom.

3 You can go slowly, Ms. Johnson.

4 Find it. It's a new argument. It's a day of closing
5 argument about how they couldn't have done it because there
6 was a government agency supposedly babysitting them. It's
7 a -- and that is the type of argument that a company makes
8 when they're caught and they have to come up with something
9 new in closing.

10 There's no way that I can possibly keep up with all of
11 the stories. It's not possible. At some point I have to put
12 my trust, we have to put our trust in you.

13 You can tell when someone's telling the truth. You can
14 tell when a company is being consistent, when they're making
15 sense. You can tell that. I'm confident of that. And I
16 don't think that I have to spent the time to go through every
17 single thing that Janssen's counsel just said in closing to
18 convince you of that. Because if we haven't done it by now,
19 we have fallen down on the job.

20 But a few things. Please bear with me.

21 Debbie Kenworthy. Let me just explain one issue to
22 you, just as an example. We have Glen Mattes, the former
23 president of the company, telling you that it's off-label
24 marketing to minimize a side effect. We have Glen Mattes
25 testifying that, yes, the sales force, the MIR request that

1 they generated, was a metric that was used to judge their
2 performance.

3 We couldn't do better than that. You can't do better
4 than getting the president of the company to admit something
5 that is that bad for them.

6 What happens? They spend the rest of the trial pulling
7 in people from data analytics to say that it didn't happen.
8 Debbie Kenworthy, she took the stand. She's very nice, I
9 thought. She works in data analytics, and she's in marketing.
10 That's a marketing function that helps them sell their drugs.
11 And the argument is if Debbie Kenworthy -- if this was a
12 nationwide scheme to promote off-label drugs, Debbie Kenworthy
13 and her data analytics in the marketing department, not
14 compliance, the marketing department, would have caught them.

15 Debbie Kenworthy came over with Candice Long from
16 Risperdal. The same data analytics used to sell and market
17 that drug off-label and to pay kickbacks to doctors that
18 landed another corporate integrity agreement in 2013. You can
19 see it for yourself. Risperdal.

20 So the techniques that they were using in marketing
21 were going to catch Janssen this time when the last time they
22 were over a drug they got caught and entered into a corporate
23 integrity agreement with the government.

24 I can't -- I can't think of a worse argument to make,
25 but I can't stamp them all out because they'll just make

1 another one.

2 You know, lawyers, we're not witnesses. It's not about
3 us. Okay? Every time there's a suggestion that someone who
4 signed a declaration because it was written by the lawyer,
5 what do you think we're all thinking? I mean, what do you
6 think that implication is? The way it works in the law is you
7 interview somebody, they write down -- they tell you all of
8 their information. You write it for them. You give it to
9 them. They review it. And if it's true, they swear to its
10 accuracy under oath.

11 Lawyers don't make up the facts for the witness, but
12 that's the implication every single time. Every time. There
13 are witnesses here, witnesses there, but the lawyers did it.
14 Witnesses don't write their own declarations. They swear to
15 their accuracy.

16 Sometimes -- here's another one I'll show you.

17 Can you pull up the instruction on the states, please,
18 Ms. Johnson.

19 You'll get an instruction in the jury verdict that the
20 state law claims are analogous to the False Claims Act. And
21 so if you find a violation of the False Claims Act, it's
22 automatically a violation of the state False Claims Act.

23 And then the question is, why didn't we hear about all
24 the states? We don't have to put on evidence of a violation
25 of the False Claims Act in each and every state. Because if

1 they violated it nationwide, you're instructed, "Therefore, if
2 you find that Janssen violated the federal False Claims Act,
3 you must also find Janssen violated the analogous provisions
4 of all of the states' False Claims Acts."

5 Now, Janssen knows that that instruction is in the jury
6 verdict -- in the jury instructions. They know this, right?
7 It's Instruction Number 23, State Law Claims. You'll get it
8 when you go back there.

9 And so the argument is, why didn't we hear anything
10 about the states? That's just to distract you. It's a
11 complete distraction, and they just hope we won't have time to
12 address it. Obviously we're not going to put on evidence
13 about what took place in Wyoming. It took five and a half
14 weeks to prove to you what took place nationwide.

15 "If you find they violated the federal False Claims
16 Act, you must also find they violated the analogous provisions
17 of all the states' False Claims Act." That's the instruction
18 you get from the Court. So why would we talk about Colorado
19 or Wyoming? It's a federal False Claims Act case.

20 Let's go to the next slide, if we could, please.

21 You know, in cases like this, the only way to prove
22 Anti-Kickback Statute violations in a nationwide off-label
23 scheme like this is to bring in witnesses and go document by
24 document by document internal to the company that show you
25 what was going on from the top down. We call the president.

1 We call the national sales director. We show you the strategy
2 documents, the forecast, the communications, the emails, what
3 took place. Not parts of them. They're all in evidence. We
4 put them into evidence. You can review them. Not this part
5 or that part but all of it.

6 And at the end of the day, at the end of the day, when
7 you prove something like that, the only way to do it is to
8 then take the statistics, get the data from CMS, bring in a
9 damages expert, bring in data analysts, and we did all of
10 that. Show statistically how doctors who are contacted
11 prescribed at a much higher rate off-label. Of course it
12 works. Right? Of course it works.

13 Think about what they said. Think about what they said
14 at one point. "Doctors make their own independent prescribing
15 decision, nothing to do with sales reps." You heard that.
16 Right? "Doctors make their own independent prescribing
17 decisions, nothing to do with sales reps." She's pointing out
18 a recording where the sales rep for Janssen is in with the
19 doctor delivering a lipid-friendly message.

20 So doctors aren't influenced by sales representatives,
21 but Janssen employs sales representatives to market to
22 doctors. Does that make sense to you? Does any of that make
23 sense? Who would make that argument?

24 Of course doctors are affected by marketing messages.
25 That's why they do it. Of course doctors can be influenced by

1 money. They may not even know it. That's why every
2 institution from every one of the doctors who they called to
3 the stand prohibits their doctors and the hospitals from
4 joining a promotional speaker bureau. All of them. Harvard,
5 Mass General, Boston, UCLA. You can't do it because they're
6 worried about it corrupting a judge -- the judgment of the
7 doctors.

8 And yet, at the end of the day, they'll say, Hey, we'll
9 call these -- we'll call four doctors out of 5,177 who were
10 influenced, we'll call four of them, and they'll convince you,
11 they think that they weren't marketed to off-label.

12 And so case over.

13 It's Janssen's intent, it's Janssen's promotion that's
14 illegal. Janssen's off-label promoting is what's illegal, and
15 that's what we have to prove. So we use witnesses that worked
16 there. We use documents from Janssen to show what they were
17 up to. And there's no other way to do it. There's no other
18 way.

19 At the end of the day, if you believe that Janssen was
20 not engaging in the off-label conduct that they demonstrated
21 in their documents, that their witnesses admitted to, that the
22 witnesses who we called all said we did it -- I mean, think
23 about that. Ms. Brown said, counsel said specifically,
24 Ms. Penelow, Ms. Penelow did not off-label market to this
25 doctor. Well, yes, she did. You know how you know that?

1 Because she did it herself daily. They all did. And they all
2 owned up to it. We did it. That was our instructions.

3 So how does Janssen say, No, Ms. Penelow, you did not
4 off-label market to that doctor? At some point, we just have
5 to trust in the process. There's no way we're going to be
6 able to disprove everything they say when they keep changing
7 their story.

8 I'll show you the first request for admission that was
9 sent to Janssen in this case. All right? And this is -- so
10 you know, this is a microcosm. This is what we're dealing
11 with. This is why Ms. Penelow and Ms. Brancaccio have been
12 fighting this case for so long.

13 Look at the first request for admission that was sent
14 to Janssen in this case. "Admit that the company promoted
15 Prezista to doctors as being lipid neutral or lipid friendly,
16 meaning that the drug would not increase a patient's
17 cholesterol, low density lipoprotein or triglyceride levels."

18 Now just a minute ago you heard, It's fine. It's okay
19 to use adjectives like "lipid friendly." They denied that
20 they ever did it. The first request for admission in the case
21 they said, We didn't do that. Now you've heard their
22 witnesses get on the stand, we have them on recording, lipid
23 friendly, lipid neutral. This was the message being pushed on
24 recording. Nancy Bartnett. Yes. And now the story is it's
25 fine.

1 They denied number 1 like they did everything else in
2 this case, denied, denied, denied. And when you prove it,
3 they change their story and say, Well, that was okay. What
4 about this? That was okay. What about this? At some point
5 in this human experience, we have to just trust that you will
6 call them out.

7 That's all we can do.

8 If we turn again to the damages in this case, what do
9 you think every defendant in a whistleblower False Claims Act
10 case says about the whistleblower? What do you think every
11 one of them says? You're just in it for the money. You're
12 just in it for the money. Every one of them says that, right?
13 Every time. You're just in it for the money. Says the
14 company who is just in it for the money.

15 They want to keep it, and they want you to focus on the
16 fact that returning money to the government is somehow the
17 reason and the only reason that Ms. Penelow and Ms. Brancaccio
18 brought these claims 12 years ago. Of course. Right? Of
19 course. And that explains what about Donna Graham? That
20 explains what about Matt Grooms?

21 I can't explain it for them.

22 They said, Boy, some of the claims were identical.
23 Yes, some of the claims in the declarations were identical.
24 Donna Graham and Mark Wilhelm filed their own case, not
25 knowing that Chrissy and Jessica had filed this one. They

1 took their claims, and they filed them afterwards. And so
2 there was a first-to-file bar. They realized this was the
3 first filed case, and they had to dismiss it. They made
4 identical allegations, wrote up 25-page declarations, and
5 swore to them in this case.

6 And they say, On the one hand, boy, all of your claims
7 were really consistent, like, that's fishy. And then in the
8 next breath, they say, But even these people couldn't agree on
9 everything. Well, which is it? Were they all in cahoots
10 saying the same thing? Or were they riddled with
11 inconsistencies telling you something different? It's
12 whatever argument they need to make right at the time they're
13 making it to get out of being held accountable for their
14 conduct. And you can't catch somebody like that unless you
15 have a jury. That's it.

16 Another one -- here's another one. Medicare Part D.
17 Nobody from CMS --

18 Can you turn to 1188, please, Ms. Johnson. 1188.

19 Why didn't you call someone from CMS? CMS does not pay
20 for drugs that are not reasonable and necessary. That's the
21 rule. They don't -- they don't do it.

22 And at the end of the day, it's in their guidelines.
23 You can look at them yourself. We don't have to call somebody
24 when Janssen's own documents specifically say that if the
25 government catches you engaged in off-label promotion and

1 violations of the Anti-Kickback Statute, you're going to get
2 in trouble, and you have to pay the money back. It's that
3 simple. It's that simple.

4 At the end of the day, I don't know -- promoting
5 off-label is unlawful. Okay? Writing a prescription if
6 you're a doctor for something that is off-label is not. If
7 it's reasonable and necessary, you can get reimbursed for it.
8 Nobody is accusing doctors. It's Janssen's influence on the
9 process that corrupts the doctor's medical judgment. And if
10 we haven't made that clear, I don't know how else we can do
11 it. The focus is on Janssen, and they keep hiding behind
12 doctors. And they'll do that until the end of time. They'll
13 say that doctors exercise their independent medical judgment.

14 Now, sales force go out and promote. I mean, they
15 literally give them sales materials that say, "low lipid
16 profile, go into doctors' offices," and then they come into
17 court and say that doesn't work. Doctors ignore them. I
18 don't know what to do about that. Does that make any sense to
19 you at all? Of course it works.

20 CMS -- this is in 1188, these are the CMS guidelines --
21 "does not pay except for smoking cessation drugs. Part D
22 drugs must be prescribed for the purposes allowed under 1862-A
23 and 1927-D-2 reasonable and necessary guidelines.

24 And that is what is Dr. Glatt provided testimony on.
25 In this case, it is not reasonable and not necessary to

1 promote this drug and to minimize its side effects when there
2 were other alternatives for patients with a lipid issue. It's
3 that serious.

4 And what else did he say? What did he tell you, the --
5 literally the only expert the Court admitted to testify about
6 these requirements? Dr. Glatt. The chief at Mount Sinai of
7 the -- of the virology section. For the longest time what did
8 he tell you? He got up there and told you their lipid message
9 was false. He had read the letter from DDMAC. He knew that
10 it was false and what they were doing was misleading to other
11 doctors and it offended him. It was false and misleading.

12 If he doesn't think that messages from a company like
13 Janssen are going to influence doctors, why would we have --
14 why would he be worried about it? He saw the letter from
15 DDMAC to Janssen saying that the slide decks and the
16 information that they have about lipids are, in fact,
17 misleading. That's the FDA's conclusion. That's not my
18 conclusion alone. That's what he told you from the witness
19 stand.

20 And why was he worried about this? Because patients
21 with lipid issues were shown to have harm if they were on
22 Prezista instead of Reyataz, and it offended him.

23 There's a paper in 2007 published at one of the
24 retrovirus conferences that specifically shows that outcome of
25 cardiac events, no longer lipid problems, but the cardiac

1 injuries were higher in the Prezista group than in the Reyataz
2 group, and it offended him.

3 Dr. Glatt does not take pharmaceutical money. He does
4 not want misleading messages going out to doctors. At the end
5 of the day, that's why we have laws against off-label
6 promotion: So you don't favor money over profits.

7 If Janssen's promotional speaker bureau was not a
8 vehicle for funneling cash and kickbacks to doctors, I'd ask
9 you to think about what is. Do they think it's just where you
10 put a satchel of cash together and hand it to a doctor in a
11 dark alley? This is the way it works. You have seen the veil
12 pulled back. This is the insidious side of what ought to be a
13 celebration, science prevailing over disease. It ought to be.
14 But, unfortunately, there's a seedy side of the business, and
15 that's the side of the business that this business unit
16 decided to capitalize on.

17 And at the end of the day, they will fall back on the
18 drugs when they were used for people that needed them and
19 ignore the fact that there were many people who were given
20 these drugs who did not, for whom they were bad, and they
21 should not have been reimbursed for that from the federal
22 government.

23 Ladies and gentlemen, I'm going to show you one more
24 time how much money they made off of these drugs and what a
25 small proportion of that amount the Relators are asking you to

1 award. They made 3 billion just during this time period. And
2 it's only the amounts tied to the kickbacks and the off-label
3 promotion that are being asked for back from the government.
4 Only those amounts. Less than a quarter. Less than a
5 quarter. And they don't want to do it. They don't want to do
6 it.

7 As you work your way through the instructions, you'll
8 be asked to pick a foreperson today. Work your way through
9 the instructions, if you possibly can, and notice -- notice
10 how the instructions conform, how the law conforms with what
11 we have been saying in this case from the very get-go. Just
12 notice how the law conforms, if there's a link in the chain.
13 If you make a payment and there's a link and the prescription
14 is written and you make money off of it, you're liable. That
15 has to happen. If there's a substantial factor associated
16 with your off-label promotion and you get caught and there's
17 reimbursement for it, you have to return the money. It's that
18 simple.

19 But I can't keep lecturing you. We've been here for a
20 long, long time, and you've been here for a long, long time.
21 I can only send you off with our best wishes, and I can only
22 hope that over the course of the last five and a half weeks
23 you at least feel like we've done our best to represent our
24 clients because, you know, it's been a long run. It's been a
25 really long run, and we can see the finish line.

1 And fundamentally, there's a hope from this side of the
2 room that justice always prevails in the long run. There's a
3 hope that it will prevail this time, and we can see the finish
4 line, but we need you to carry us across it. Deliver justice
5 for Janssen. Make sure they don't do this again. Make them
6 return the money. Don't let them do this again.

7 Thank you, ladies and gentlemen. I appreciate your
8 time.

9 THE COURT: All right, thank you.

10 Members of the jury, that time has come. All right.
11 I'm going to put this case in your hands. But before I do, I
12 have very brief remarks regarding the deliberations process
13 that I generally wait until now to tell you so you understand
14 what you're going to do when you go to the room.

15 I've given you final jury instructions earlier today
16 explaining the law regarding the testimony and other evidence
17 and the claims Relators have brought against Janssen. Now let
18 me explain some things about your deliberations in the jury
19 room and your possible verdicts.

20 The first thing that you all need to do when you go
21 into the jury room is select one member of the jury as your
22 foreperson. That person will preside over the deliberations
23 and speak for you here in open court. Folks, if you do
24 nothing more today -- and I'll get to that later in this brief
25 instruction -- that, I need to you do. I need you to pick

1 your foreperson so I have somebody who's communicating on
2 behalf of the jury with the Court. And so that, I'm going to
3 ask you to do before anything else is done, even if you're
4 going to be excused for the rest of the day.

5 Now, you have two main duties as jurors. The first one
6 is to decide what the facts are from the evidence that you saw
7 and heard here in court. Deciding what the facts are is your
8 job, not mine, and nothing that I've said or done during this
9 trial was meant to influence your decision about the facts in
10 any way.

11 Your second duty is take the law that I gave you, apply
12 it to the facts, and decide if under the appropriate burden of
13 proof the Relators have established their claims.

14 It is my job to instruct you about the law, and you are
15 bound by the oath that you took at the beginning of this trial
16 to follow the instructions that I give you, even if you
17 personally disagree with them. This includes the instructions
18 that I gave you before and during the trial and the final
19 instructions that I gave you right before closing arguments.
20 All the instructions are important, and you should consider
21 them together as a whole.

22 Perform these duties fairly. Do not let any bias,
23 sympathy, or prejudice that you may feel toward one side or
24 the other influence your decision in any way.

25 As jurors, you have a duty to consult with each other

1 and to deliberate with the intention of reaching a verdict.
2 Each of you must decide the case for yourself, but only after
3 a full and impartial consideration of all the evidence with
4 your fellow jurors. Listen to each other carefully.

5 In the course of your deliberations you should feel
6 free to re-examine your own views and to change your opinion
7 based upon the evidence. But you should not give up your
8 honest convictions about the evidence just because of the
9 opinions of your fellow jurors. Nor should you change your
10 mind just for the purpose of obtaining enough votes for a
11 verdict.

12 No one will be allowed to hear your discussions in the
13 jury room, and no record will be made of what you say. You
14 should all feel free to speak your minds.

15 When you start deliberating, do not talk to the jury
16 officer or to me or to anyone but each other about the case.
17 During your deliberations, you must not communicate with or
18 provide any information to anyone by any means about this
19 case. You may not use any electric device or media, such as a
20 cell phone, smart phone, computer of any kind, the internet,
21 any internet service, or any text or instant messaging service
22 or any internet chat room, blog, website, or social networking
23 service to communicate to anyone any information about this
24 case or to conduct any research about this case until I accept
25 your verdict.

1 You may not use these electronic means to investigate
2 or communicate about the case because it is important that you
3 decide this case based solely on the evidence presented in
4 this courtroom. Information on the internet or available
5 through social media might be wrong, incomplete, or
6 inaccurate. Information that you might see on the internet or
7 social media has not been admitted into evidence, and the
8 parties have not had a chance to discuss it with you. You
9 should not seek or obtain such information, and it must not
10 influence your decision in this case.

11 Now, if you have any questions or messages for me, you
12 must write them down on a piece of paper, have the foreperson
13 sign them, and give them to the jury officer. And just to be
14 clear, it's not going to be a random piece of paper. You are
15 going to be provided with what's called jury communication
16 forms. That's the document you're going to use to communicate
17 with me if you have a question or to communicate something to
18 the Court. Then you'll provide that to the CSO, who is going
19 to be outside. That CSO will bring it to the courtroom
20 deputy, who will bring it to me. And that's how you all
21 communicate with me. And make sure that the foreperson has
22 signed those statements.

23 Again, the court -- security officer will give them to
24 me, and I will respond as soon as I can.

25 Now, depending on what you communicate to me, folks, I

1 may have to talk to the lawyers about what you've asked and so
2 it may take me some time to get back to you.

3 What I would ask of you in that circumstance is, in the
4 meantime, if possible, continue with your deliberations on
5 some other subject until you hear back from me on the question
6 that you've posed.

7 One more thing about the messages. Never write down on
8 these jury communication forms or tell anyone how you stand on
9 your votes. For example, do not write down or tell anyone
10 that a certain number is voting one way or another. Your vote
11 should stay secret until you are finished.

12 Additionally, your verdict must represent the
13 considered judgment of each juror. In order for you as a jury
14 to return a verdict, each juror must agree to the verdict.
15 Your verdict must be unanimous.

16 A form of verdict or a verdict sheet has been prepared
17 for you. I will have that verdict form brought to you along
18 with the jury instructions, exhibits, and other evidence that
19 is going to be brought to the deliberations room. Also
20 included are those jury communication forms that I just
21 referenced.

22 The verdict form has a series of questions for you to
23 answer. When you have reached unanimous agreement as to your
24 verdict, you will fill it in and have your foreperson date and
25 sign the form and then send a jury communication that states

1 that you have reached a verdict.

2 Let me be clear about that, just so there's no
3 miscommunication.

4 If you've reached verdict, at whatever point you do,
5 you send me a communication that simply states, We have
6 reached a verdict, or words to that effect. Do not send me
7 the verdict form. That will be done in open court, and
8 there's a process for that.

9 So if I receive that jury communication that you've
10 received -- that you've reached a verdict, that will come to
11 me. You'll then return to the courtroom, and at that point,
12 I'm going to speak with the foreperson. I'm going to ask
13 first if the jury's received a verdict, is it unanimous. I'm
14 then going to ask to see the verdict form, and that form is
15 going to be provided to me to inspect.

16 I'll then, as long as my inspection says it's okay,
17 it's been completed properly, we'll return it to the
18 foreperson, and then I'm going to ask the foreperson about the
19 verdict. And that will be how we are going to deliver that in
20 the courtroom.

21 Once again, I want to remind you -- excuse me. I'm
22 sorry.

23 Unless I direct you otherwise, do not reveal your
24 answers until you are discharged. After you have reached your
25 verdict, you are also not required to talk with anyone about

1 the case unless I order you to do so.

2 Once again, I want to remind you that nothing about my
3 instructions and nothing about the verdict sheet or form of
4 verdict is intended to suggest or convey in any way or manner
5 what I think your verdict should be. It's the sole exclusive
6 duty and responsibility of the jury to determine the verdict.

7 Now, I asked that all the jurors still be in the
8 courthouse by 9 a.m. as we have been doing that for the trial.
9 And so depending on you guys coming in tomorrow, what I'm
10 going to ask you to do is to come in, meet as you normally do.
11 You'll be called into the courtroom, and then I will dismiss
12 you to go deliberate.

13 What I want to make sure you all understand, too, and
14 appreciate is you all have to be in the room to deliberate.
15 You can't have it -- you come in in the morning and some of
16 the jurors are there but you're waiting on some others, do not
17 discuss the case. All eight of you have to be in the room.
18 If somebody steps out to go to the restroom, stop talking
19 about the case until that person returns.

20 So the process will be in the morning you'll be called
21 in at 9 a.m. I'll basically tell you folks that you're
22 dismissed to continue to deliberate, and then you'll begin
23 your deliberations in the morning.

24 Also, one other point about timing. As opposed to the
25 schedule for the trial, which ended at either 4 p.m. or 5

1 p.m., depending on the day, you're encouraged, but not
2 required, but you're encouraged to continue deliberations past
3 5 p.m. I am going to let you know, though, there is a cut
4 off. By 7:30 p.m., I can't permit you to continue
5 deliberations. We have court security officers that are here
6 until 8, and I want to make sure that all of you get out while
7 we still have security in the building and we can close up
8 properly.

9 So at no point am I going to allow you to continue to
10 deliberate past 7:30 p.m.

11 One other thing, folks. If the jury wants to
12 deliberate longer because you're discussing issues, you want
13 to work through a certain discussion, you absolutely have that
14 prerogative.

15 So that's how that will work for each day. There's no
16 set time at which you need to conclude your deliberations
17 other than the 7:30 p.m. time that I just told you, but I'm
18 going to ask that you alert me each day when you do using your
19 jury communication form, because I'm going to want to close
20 out each day knowing when you guys are done.

21 For example, for this evening, I'm not asking you to do
22 anything more for me other than to pick your foreperson. So
23 I'm going to ask you to do two things. One is, when I excuse
24 you, pick your foreperson, and I'm going to be sitting here
25 waiting for a communication. That communication is either

1 going to say, Judge, we'd like to just start fresh in the
2 morning, it's been a long day, or words to that effect, that
3 you want to stop and continue deliberations in the morning, or
4 you're going to send me a notice shortly after you go in there
5 to pick your foreperson that says, We'd like to continue our
6 deliberations.

7 If I get that, we know you're going to be in there for
8 a bit, and then we'll wait for a communication. And if
9 there's no other communication, then I presume there will be
10 one that says, We're done deliberating for the day. That
11 communication has to come to me, if not before 7:30, at 7:30
12 p.m. because that's when I'm telling you you need to be done.

13 So that's all I need you to do for today. I'm not
14 going to ask you in the court and get a poll of who wants to
15 stay longer, who's done for the day. You all go in there,
16 pick your foreperson, discuss it privately, and send me a
17 communication that tells me how do you want to proceed today.
18 Are you done, or would you like to continue to deliberate?
19 And you have that prerogative, and I will permit you to make
20 that choice for yourself. I'm not going to make it for you.

21 At this time, I'm going to ask the jurors sitting in
22 the box to please rise, be escorted out of the courtroom and
23 into the jury room.

24 But before I do that, I'm sorry, Patty, can you swear
25 in the court security officer.

1 You guys can stand. We're about to leave, but I need
2 the court security officer sworn in because that's the person
3 that's going to be outside your deliberations room.

4 (COURT SECURITY OFFICER WAS SWORN AT THIS TIME.)

5 THE COURT: Thank you. Folks, you're going to be
6 escorted out by Patty. And there will be some documents and
7 exhibits and other things coming in, but for now, you do what
8 I asked. Get me a foreperson and communicate whether you're
9 going to stick around and you need to leave for the day.

10 Thank you.

11 (The jury exits the courtroom.)

12 THE COURT: Folks, everybody have a seat. Let me
13 wait for the door to shut.

14 Folks, anything we need to discuss on the record before
15 we go off and wait for the jurors to find out whether they
16 want to continue deliberations or start fresh in the morning?

17 Mr. Marketos?

18 MR. MARKETOS: No, Your Honor. Not from our side.
19 We're good.

20 THE COURT: Ms. Brown, anything from Janssen?

21 MS. BROWN: No, thank you, Judge.

22 THE COURT: All right. Why don't we do this, then.
23 We are in recess for a few minutes, but I would ask that you
24 guys stay in the courtroom or close by because that
25 instruction is probably likely to come, and I don't know if

1 they're done for the day or we're going to be sticking around
2 for another hour or so.

3 So do you mind just sticking around? If you all need
4 to go to the restroom or take a personal break, that's fine to
5 step out, but everybody stick around. And I'm going to step
6 off the bench, and you folks can remain seated.

7 (A short recess occurred.)

8 THE DEPUTY COURT CLERK: Remain seated.

9 THE COURT: All right, folks, we received jury
10 communication number 1. Do you want me to wait? I don't even
11 know if everybody is here. It's nothing -- it's what was
12 expected.

13 But -- so I received jury communication number 1. It
14 reads: "We have selected foreperson number 4. We'll be done
15 for the day."

16 I don't know why they told me who they selected, but
17 they did write that in the communication, so I'm putting that
18 on the record. And then they wrote, "We'll be done for the
19 day."

20 My intention, based on this communication, is to excuse
21 them, have them come in fresh at 9 a.m., bring them into the
22 courtroom, and then excuse them to the jury room to begin
23 their deliberations fresh in the morning.

24 Anything we need to chat about before I bring them in
25 and excuse them for the day?

1 MR. MARKETOS: No, Your Honor. Thank you.

2 MS. BROWN: No, Your Honor.

3 THE COURT: All right. Let's go. Let's get them.
4 And like I said, after I excuse them for the day, if there's
5 anything more we need to talk about, we will.

6 THE DEPUTY COURT CLERK: All rise for the jury.

7 (The jury enters the courtroom.)

8 THE COURT: All right. This is going to be brief.
9 We received jury communication 1 that you selected foreperson
10 number 4 and we'll be done for the day.

11 You are excused for the day. I'll see you all here
12 tomorrow at 9. Just make sure that you do not deliberate
13 until you come into the courtroom, I then dismiss you to the
14 room, and then you can begin really talking about this case
15 fresh in the morning.

16 Again, thank you for your attention and your time, and
17 I appreciate that. And I'll see you all tomorrow morning.
18 You're excused.

19 And folks, afterwards, just remain. I just don't know
20 if we have something we need to chat about before we adjourn
21 for the day.

22 (The jury is excused at 5:41 p.m.)

23 THE COURT: Folks, have a seat.

24 All right, folks. I don't know if we have anything to
25 talk about now. We just should wait for the jurors tomorrow

1 morning, and we'll start fresh.

2 But anything we need to chat about or any new issue
3 that we need to address either tomorrow morning or otherwise?
4 But I'm not going to address it now, but if you want to give
5 me a heads-up, we can talk about it tomorrow.

6 From the Relators, first, or do you guys need to confer
7 on something?

8 MR. RUSS: No, Your Honor. I wanted to say, on
9 behalf of the Relators team, thank you so much for a great
10 trial. And I'm not trying to suck up. It was a just a great
11 experience in front of you.

12 THE COURT: No, no. I appreciate that.

13 And I don't know if, Ms. Brown -- you don't even have
14 to agree with them, or Mr. Wyatt. I'm saying, is there
15 anything we need to talk about before we get back to the jury?

16 MS. BROWN: Nothing we need to talk about, but we
17 absolutely agree. Thank you and your staff as well, Judge,
18 for six weeks of helping us. We appreciate it.

19 THE COURT: All right. Well, I appreciate you guys,
20 too.

21 And look, I would be remiss if I didn't mention
22 something about counsel on the record. I'm going to do that,
23 even though I think I mentioned something earlier. I don't
24 now what day that was, but I know I commented before, but I
25 think it bears repeating.

1 I think counsel from both sides have really just been
2 absolutely exceptional during the trial. I really do. I'm
3 talking -- when I say that I'm talking about well prepared,
4 professional, and very strong in your advocacy, especially
5 when you're in the well in a courtroom. And I appreciate that
6 both counsel have zealously advocated for your clients.

7 And it's worth also noting, and I think this is
8 important, not just for you but for your client, the courtroom
9 has been fairly busy the last five and a half weeks while
10 you've been trying this case. And I know you don't pay
11 attention a lot to that, and I don't spend a lot of time
12 paying attention to it, but I can see behind you when you're
13 looking at the jury or cross-examining or directing a witness.

14 We have begun our judicial intern program in this
15 courthouse. I can't tell you how many judicial interns, not
16 only from my chambers, from my colleagues' chambers, who have
17 been in this courtroom to watch this trial. The law clerks,
18 the judicial law clerks, not only from my courtroom, which are
19 working on the case, but from my colleagues, both district
20 judges and magistrate judges, have been in this courtroom to
21 observe this trial.

22 Some of my own colleagues, who you may not have
23 recognized that are judges in this courthouse, have been in
24 this courtroom to observe the trial that you guys have been
25 presenting in this case for the past five and a half weeks.

1 And I'm telling you, there's only two reasons why folks
2 come into a courtroom. It's either because they're told,
3 You've got to go see what never to do ever in your careers, or
4 You really need to go see this trial. They're outstanding
5 lawyers that are representing both sides, and it's a really
6 educational opportunity for the courthouse, and I'm telling
7 you it's the latter. Right? We have had folks comment about
8 the performances of both Relators' counsel and defense counsel
9 throughout the past five and a half weeks.

10 So I'm just saying on the record I have nothing
11 invested in this verdict, I have nothing invested in who's
12 going to raise issues on my decisions in the trial -- and that
13 honestly means nothing to me. That's in the rearview mirror
14 for me. But I wanted you all to know, folks in Texas, you're
15 always welcome back into my district in my courthouse, and the
16 folks from Skadden across the river again, I look forward --
17 I'm sure I'm going to see you all on a different, unrelated
18 case, but I look forward to seeing you all as well.

19 And I wanted to say both of that. I didn't want to do
20 that in the presence of the jury. I thought it was more
21 appropriate to say it on the record for you, and also for the
22 benefit of your clients and your colleagues who may not know
23 what the heck you've been doing here for the last almost six
24 weeks.

25 And I also know that I pushed you folks. You know, 9

1 to 5 is not an easy trial schedule with a 30-minute break.
2 And I did that, in part, because I really wanted this case to
3 go on time to the jury. I hope you recognize that this jury
4 is in very good spirits five and a half weeks in. And I tell
5 you that's important because my take on a jury is it's always
6 best so that you can get a verdict if they can work together.
7 If they're in good spirits, they can reach some decision on a
8 case. And so I hope you appreciate that I did push you more
9 so than I've done other folks. I hope you also understand
10 that I pushed you folks because I believe that you guys were
11 capable of being pressed to try a case in that manner.

12 So I did want to place it on the record. If there's
13 nothing further, I'm going to adjourn for the day.

14 But, folks, do you think we just meet at 9 a.m., or do
15 we need to meet at 8:30 in case there are things that have
16 come up?

17 I'm going to defer to counsel. I have no problem
18 meeting at 8:30, but I also think you all need some rest. So
19 if that extra 30 minutes is important to you, we can meet at
20 9 o'clock. You tell me.

21 MR. MARKETOS: 9 would be great, Your Honor.

22 MS. BROWN: That would be terrific. Thank you,
23 Judge.

24 THE COURT: All right. I will see you all at 9. Be
25 well. Folks, remain seated.

1 THE DEPUTY COURT CLERK: All rise.
2 (Court concludes at 5:46 p.m.)
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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

- - - - -

I certify that the foregoing is a correct transcript from
the record of proceedings in the above-entitled matter.

I

/S/ Megan McKay-Soule, RDR, CRR

June 11, 2024

Court Reporter

Date

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